

Pharmaceutical/Biotechnology Industries

Overview

Typically, the Pharmaceutical and Biotechnology industries are considered separate and distinct industry sectors. This Health Care Information Sheet includes both sectors within the one worksheet. While the sectors and typically many variables about individual companies (size, revenues, number of products, etc) do vary, from an ITP's perspective, many of the job functions within the two sectors actually are very similar. Hence, section 3.0 below, "Details on Various Occupations" is valid for both sectors. However, independent labour market, and Links are provided for each sector.

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3.0 Details on Various Occupations

- 3.1 Researcher – R&D
 - Clinical Researcher (*see separate information sheet #20*)
- 3.2 Microbiologist and Immunologist
- 3.3 Biotechnology Technologists
- 3.4 Medical Information Associate
- 3.5 Regulatory Affairs Associate
- 3.6 Biostatistician

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1.0 Pharmaceutical Industry

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1.1 Introduction

1.1.1 Pharmaceutical Industry Definition

Source:

- (1) *Pharmaceutical and Medicine Industry HRSDC, Industry Profile , 2004*
- (2) *Report of the BIOCouncil: Building Ontario's Biotechnology Corridor, 2002*
- (3) *Biotech Ontario, Shaping The Future: Biotech Clusters, 2004*

This industry group comprises establishments primarily engaged in manufacturing drugs, medicines and related products for human or animal use. The Canadian brand name pharmaceutical industry is a group of about 80 multinational companies concentrated in the Toronto and Montreal metropolitan areas. The major companies in this group have pharmaceutical research and development operations and undertake basic, clinical and applied research in intramural and extramural programs.

Major segments within the pharmaceutical sector include:

- brand-name drug manufacturers,
- generic drug manufacturers,
- firms developing biopharmaceutical products,
- non-prescription drug manufacturers,
- firms undertaking research on a contract basis.
- Canadian universities, hospitals and research centers also play a pivotal role in the research and development activities of this sector.

Establishments in this industry may undertake one or more of several processes, including basic processes, such as chemical synthesis, fermentation, distillation and solvent extraction; grading, grinding and milling; and packaging in forms suitable for internal and external use, such as tablets, vials, ampoules and ointments.

Source: <http://www.abpi.org.uk/education/careers.asp>

Stages involved in getting a drug to market:

- Drug discovery
- Drug patent
- Chemical and pharmacological development, toxicology
- Clinical trials
- Manufacturing
- Registration and regulatory affairs
- Sales and marketing
- Post marketing surveillance

1.1.2 General Areas

Ideally candidates possess a blend of scientific and technical training, basic business skills, and knowledge in related areas such as intellectual property and regulatory affairs.

The industry has a wide range of skill requirements, including entry-level and senior researchers, technicians, engineers, scientists and management, as well as experts in

areas as diverse as intellectual property, quality assurance, informatics and marketing.

Source: *Excerpted and adapted from <http://www.ncbiotech.org/ncindustry/careers/jobresc/jobtypes.cfm>*

1.1.2.1 Research & development

Scientific research is the basic foundation of any high-technology industry. New ideas represent the company's future because they lead to a continuing line of new products. In some companies, research focuses on specific applications or products: how to apply scientific knowledge in new ways or how to improve an existing product. In other companies with large budgets, some research teams carry out basic scientific research with no immediate application. These companies believe that simply acquiring new knowledge and understanding of how living systems work will pay off in the long run with new product ideas.

While biotechnology companies have their own research teams and often contract with other companies for specialized work, much of the research that drives industrial progress is carried out in universities by academic scientists.

Once a promising idea is generated, it is refined and made practical in a process known as product development. Scientists and engineers address issues such as how the product will look and work and how it can be manufactured most efficiently and cheaply on a large scale.

The entire process of research and development is a substantial effort. The typical new pharmaceutical product can take 10 or more years to develop and total development costs total at least \$500 million.

Various Job Titles

Pure Science

- Distinguished Research Fellow, Senior Research Fellow, Research Fellow
- Research Fellowships
- Principal Scientist
- Senior Scientist
- Scientist
- Senior Associate Scientist
- Associate Scientist
- Research Associate
- Research Assistant
- Lab Assistant
- Engineer
- Toxicologists

Clinical Research

- Clinical Research Associate/ Monitor
- Clinical Research Coordinator
- Clinical Data Specialist
- Medical/Technical Writer

1.1.2.2 Production and quality control

Workers in production divisions actually make the products or deliver the services that the company sells. Large-scale production or manufacturing often require not only people with scientific expertise, but also those with knowledge of engineering or industrial-manufacturing technology.

Workers in quality-control divisions make sure that the product meets specifications. Quality-assurance personnel monitor the entire production process, and sometimes research and development operations as well, in order to ensure that correct and reproducible procedures are followed at all times. This is particularly important in the pharmaceutical industry, where the FDA [in Canada – Health Canada Drug Directorate] has established stringent guidelines for the testing and manufacture of drugs.

Various Job Titles

- Production Planners
- Manufacturing Technician
- Quality Control/Assurance
 - Quality Control Analyst
(make sure that the product meets specifications)
 - Quality-assurance Auditor (monitor the entire production process, and sometimes research and development operations as well, in order to ensure that correct and reproducible procedures are followed at all times)

1.1.2.3 Distribution

Workers in distribution divisions are primarily engaged in packaging, inventory and shipping. Some may repackage from bulk shipments for smaller retail delivery. Others may provide proprietary brand name packaging from generic products.

Product labeling needs to meet Health Canada Drug Directorate standards.

Various Job Titles

- Product/inventory management
- Product packaging
- Customer relations
- Medical/science information consultant

1.1.2.4 Administration

(i) Management

Managers at different levels in all divisions organize and supervise the activities described previously. In most of the technical divisions of a company - Research and Development, Production, and Quality Control, for example - people who become managers most often start out as scientists or engineers and work their way up. Often in biotechnology companies, the Chief Executive Officer or other high-level managers are the Ph.D. research scientists whose ideas for new products provided the initial impetus to start the company. In other companies, these scientists remain in charge of research divisions while managers with business training and experience assume other executive positions.

(ii) Regulatory affairs

Various activities of companies of all types are regulated by federal and state [provincial/territorial] agencies. This is particularly true of agricultural and pharmaceutical biotechnology companies that must comply with intricate regulations imposed by the FDA, EPA, and USDA [regulators] concerning the nature and manufacture of products. Many companies have teams of specialists, often with a scientific background, who keep track of all federal and state [provincial/territorial] regulations that apply to the company and make sure the company complies with them.

(iii) Legal affairs

One of the more important jobs for a biotechnology company is to secure patent protection for its inventions. Without a patent, a new product idea may be worthless because competitors can then make the same product. Having exclusive rights during the term of a patent to market a new invention is often the only way a company can be assured of sufficient sales to pay for the costs of research, development, and production, and still make a profit.

Consequently, companies may hire specialists to prepare and track patent applications, and larger corporations may have their own patent attorneys on staff. Many companies retain the services of external law firms, many of which now specialize in patent law for the biotechnology industry.

(iv) Public relations, communications, and training

Any company needs people who are effective communicators. Biotechnology companies in particular must be able to offer information about advanced scientific products to the lay public in an easily understandable way. Technical writers may be employed to write internal or external scientific reports.

By their very nature, high-technology industries are involved in sciences that are breaking new ground rapidly. This demands that employees be able to learn about new technologies quickly. Large corporations may employ full-time staff development personnel who organize training within the company.

(v) Support functions

As do all companies, biotechnology companies need a variety of support personnel such as secretaries, accountants, human resource personnel and computer technicians.

Various Job Titles in Administration

- Regulatory Affairs Associate (keeps track of all federal and state regulations that apply to the company and makes sure the company complies with them)
- Medical Writer (medical writers fall into two broad categories - those providing regulatory documents and those supporting sales and marketing)
- Medical Information Associate (professional who answers calls regarding drugs already on the market; keeps track of toxicity studies)
- Biostatisticians, Data Managers
- Intellectual Property Manager
- Patent Agent

1.1.2.5 Sales and Marketing

Based on its scientific research, a company may think it has a terrific product idea. But will it sell? Market researchers try to answer this question by assessing the need for the product, the number of people likely to buy it, and the price they might be willing to pay for it. Marketing personnel also try to find new markets for a product already being sold by the company, and seek new ways to advertise and promote the product.

Salespeople are in the front lines, dealing directly with customers and selling the product. Sales personnel not only make sales, but are also highly visible representatives of their company. They are often asked for technical advice about their products, and they collect feedback from customers.

In the biotechnology industry, there is a definite need for sales and marketing employees with a scientific education. These employees must understand the nature of the highly technical products they sell and must know how to communicate with their customers who often are scientists or medical professionals.

Various Job Titles

- Sales Representative (is often asked for technical advice about their products; collects feedback from customers)
- Market Researcher/Analyst (finds new markets for a product already being sold by the company, and seeks new ways to advertise and promote the product)
- Clinical Advisor (supports the sales team)
- Telemarketers
- Marketing Communications Coordinator
- Marketing Systems Analyst

1.1.3 General Educational Requirements

Source: <http://www.bhrc.ca/career/tools/teachers.htm>

Research and development: tend to require MSc's, PhD's in sciences like microbiology and applied sciences like bioresource engineering

Production: at least a BSc in microbiology or a diploma in lab technical work

Quality control: at least a BSc in microbiology or a diploma in lab technical work

Process control [quality assurance]: at least a BSc in microbiology or a diploma in lab technical work

Sales/marketing: training or a diploma in marketing, sales, or science; sometimes an MBA

Administration: training or a diploma in marketing, sales, or science; MBA's are very useful

1.2 Labour Market Prospects

1.2.1 Employment Patterns

Ontario is home to more than half the country's brand-name pharmaceutical and medical devices industries, and almost half the medical biotechnology industry.

The 1996 Census indicated an employment level in Ontario of 20,100 employees. Canada's Research-Based Pharmaceutical Companies (Rx&D) is a national association representing 24,000 men and women who work for 54 research-based pharmaceutical companies in Canada. Approximately 10,000 medical researchers are employed. Of this total, about 4,000 work within Rx&D member companies and an estimated 6,000 work at universities, hospitals and research institutions.

Key operations are run by global pharmaceutical giants such as GlaxoSmithKline, Amgen, Biogen, Genzyme, AstraZeneca, Eli Lilly and Pfizer.

Toronto accommodates 80 per cent of Canada's top high-tech businesses and is the largest cluster of biomedical and biotechnology companies in the country. In fact, over 40 percent of Canada's biotechnology industry is located in the Greater Toronto Area, one of the largest centres of medical R&D in North America. This region is recognized for its achievements and expertise in genomics / proteomics, stem cell research, photonics, drug research and development and neurosciences. Brand name pharmaceutical multinationals have invested substantially in local research and development: more than \$1.1 billion over the past decade. In addition, the Faculty of Medicine at the University of Toronto and affiliated research institutes received over \$250 million in public research funding last year alone.

Employment in the industry can be broken down into five broad categories:

- Sales and marketing
- Research and development (pure science and clinical research)
- Manufacturing (i.e., quality control/assurance)
- Distribution
- Administration and regulation

Employment in the industry is concentrated in the Toronto and Montreal areas. Ontario and Quebec account for approximately 90 per cent of industry employment.

It is the most highly educated workforce in the Canadian economy, with 44 per cent of the researchers holding Masters or Doctorate degrees.

The workforce is evenly split between males and females.

Ontario's medical devices industry

- 16,700 employees
- 585 companies
- Recorded revenues of US \$3.6 billion (CDN \$5 billion) in 2003

1.2.2 Pharmaceutical Sector Employment Trends

Source:

(1) Pharmaceutical and Medicine Industry HRSDC, Industry Profile, 2004

(2) Report of the BIOCouncil: Building Ontario's Biotechnology Corridor, 2002

(3) Biotech Ontario, Shaping The Future: Biotech Clusters, 2004

Employment Growth

Most companies expect that employee growth will occur in two areas: sales and marketing, and research and development. In addition, generic companies and some of the smaller innovative companies that are developing products will need product development and specialized manufacturing expertise, quality control and regulatory affairs expertise, and skilled production workers.

Between 1983 and 1995, employment in the sector (excluding extramural R&D) grew at an average annual rate of 2.1 per cent, rising from 15,268 to 19,657. In the early to middle 1990s, the aggregate employment level of the Canadian pharmaceutical industry was relatively stable, albeit with significant underlying shifts. Employment in some of the larger brand-name firms fell, while employment in generic companies and smaller brand-name firms (including bio-pharmaceutical firms) increased.

In 1998, Canadian average salaries and wages for this sector totalled \$44,283, substantially higher than the average for the entire manufacturing sector of \$37,850. (*Source: Strategis*)

Age

Twenty-two per cent of the workers in this sector were between the ages of 15 and 29 whereas 26 per cent were found at the national level. The majority (64 per cent) of the employees in this sector was in the 30-49 years old age bracket, while in the whole economy, there were only 55 per cent. The older workforce may be due to the higher levels of education required in this field and the recruitment of experienced workers. (Source: Statistics Canada, Census 1996)

Education Level

Higher education is a prerequisite for many occupations in this field. Forty-three per cent of the employees have a university degree and at least 85 per cent have a high school diploma (Source: Statistics Canada, Census 1996)

Labour Turnover

In 1989 to 1993, the labour turnover for the pharmaceutical industry was 10 percentage points lower than that of all industries. Since 1993, the difference between the two has narrowed. In 1996, there was only a gap of 4 percentage points. This suggests that in recent years, the job security in this sector has decreased slightly. (Source: HRDC)

Reason for Leaving

There are few layoffs in this sector. Nineteen per cent of the workers who left the industry did so because of a shortage of jobs, compared to 46 per cent for all industries. In the sector, 22 per cent quit voluntarily versus 20 per cent for all of Canada. Fifty-nine per cent left the industry for other reasons such as: sickness, maternity, and bankruptcy, as opposed to 35 per cent for the whole nation. (Source: HRDC)

Previous Jobs

Of the workers who started a job in the pharmaceutical and medicine industry, 48 per cent had worked previously in the industry. This indicates a preference for the recruitment of experienced internal workers. (Source: HRDC)

Recruitment & Recruitment Issues

Companies tend to look within the industry for employees, previous jobs held by workers who started a job in the pharmaceutical sector in 1996.

Little hiring is done from universities, primarily because companies are looking for individuals with field experience. International competition occurs for top talent. Head-hunting is common. There is increasing reliance on the Internet as a tool for recruiting.

1.2.3 Pharmaceutical Employment Opportunities

Supply problems exist with respect to expertise in:

- regulatory and government affairs
- specialized manufacturing expertise
- recruiting experienced medical doctors is a problem because of supply constraints
- Some generic companies report problems recruiting experienced chemists and product development expertise.

Overall, the supply of human resources appears to be adequate to meet anticipated demand. While firms encounter some recruiting difficulties, these tend to be isolated cases with no consistent pattern suggesting a widespread skills gap.

Turnover is quite low, and those that leave typically go to another pharmaceutical company.

Total employment in the sector over the next five years is expected to grow, as pharmaceuticals are perceived as health care solutions.

Biopharmaceutical research encompasses a wide range of scientific disciplines:

- Genetics
- Molecular biology
- Biochemistry
- Microbiology
- Physics
- Pharmacology
- Information technologies

The educational system appears to produce enough graduates to meet demand for entry level positions but skill shortfalls exist in a number of specialized research areas (e.g. biophysics, carbohydrates, and computational chemistry).

The other end of the technology spectrum requires expertise in process engineering and industrial scale-up (fermentation and downstream recovery and purification) and regulatory affairs (documentation and validation of manufacturing processes and quality control assurance); however, most of these skills are in short supply and must be imported.

The diverse range of skills required along with the dramatic pace of change is not reflected in current university courses. For example, bioinformatics requires a background in genetics, statistics, and software development, but most graduates lack such multi-disciplinary training. Also, there are no Canadian undergraduate degree programs in bioengineering; specialization options are normally offered within more traditional engineering programs. Initiatives to fill these skill gaps, include a post degree certificate program in bioinformatics launched by the Canadian Genetic Diseases Network and course requirements for an accredited degree program in bioengineering being developed by the Professional Engineers of Ontario in conjunction with the Canadian Engineering Accreditation Board.

The industry will also face an increased demand for experienced senior managers who can lead firms through strategic alliance negotiations and commercialization, and mentor younger managers. Canadian industry has not yet reached sufficient maturity to find managers with the necessary expertise. The international pharmaceutical industry has been an important source of managerial talent but there is intense competition for such managers worldwide.

General trends include;

- Increased focus on combination therapies, lifestyle pharmaceuticals for seniors, Gene therapy and DNA
- Fewer mergers are occurring now in industry

Regulatory Affairs

Source: <http://postgraduate.humber.ca/07721.htm>

The number of career opportunities continues to grow in this field. As regulatory processes increase in complexity and scope, and globalization occurs within the field, there will be continuing industry demand for people with a strong foundation in regulatory affairs. Rapidly expanding research and development efforts, and the need to increase speed to market, depend on the strategic involvement of competent regulatory affairs professionals. Graduates of the program will have an understanding of the regulatory processes in place for biotechnology, medical device, pharmaceutical and food products. In addition, the internship experience will allow students to acquire more specialized, "hands-on" experience within a specific industry.

1.3 Links

Educational Institutions

- Community college programs include: Regulatory Affairs, Clinical Research, Quality Assurance, Biotechnology Technician/Technologists and Chemical Laboratory Technology-pharmaceutical etc. See the OCAS Guide for a listing of programs.
http://www.ontariocolleges.ca/pls/portal30/url/page/OCAS_ProgramSearch_Search
- Private colleges also offer programs (i.e., Kriger Institute – Clinical Research).
- University Masters or PhD programs in the fields of science and technology are also relevant to work in the pharmaceutical industry
- In some instances ITPs are successful in securing employment in the pharmaceutical industry without further training.

Related Web Sites

- Health Products and Food Branch http://www.hc-sc.gc.ca/hpfb-dgpsa/index_e.html
- Canadian Association of Professional Regulatory Affairs (CAPRA)
- Drug Information Association (DIA) <http://www.diahome.org>
- Pharmaceutical Sciences Group (PSG) <http://www.psg.ca/>
- Regulatory Affairs Professional Society (RAPS)
- Thompson Center Watch Clinical Trials Listing Service <http://www.centerwatch.com/>
- Merck Frosst Clinical Research http://www.merckfrosst.ca/e/research/r_d/clinical_research.html
- Health Canada Clinical Trials FAQ http://www.hc-sc.gc.ca/english/media/releases/2000/2000_11ebk1.htm
- ClinicalTrials.gov Information Centre <http://clinicaltrials.gov/>

2.0 Biotechnology Industry

- 2.1 Introduction
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2.1. Introduction

Sources:

- *Biotechnology in Canada -A Regional View: February 2004 Life Sciences Branch Industry Canada*
- *2004 Canadian Biotechnology Human Resources Study Biotechnology Human Resource Council (CBHRS)*
- *Biotech Canada: State of the Industry 2004*
- *“Stepping Up”: Report of the Expert Panel on Skills, Advisory Council on Science and Technology (ACST)*
- *The Biopharmaceutical Industry: Overview, Prospects and Competitiveness Challenges, 2001, Industry Canada*

2.1.1 Industry Overview

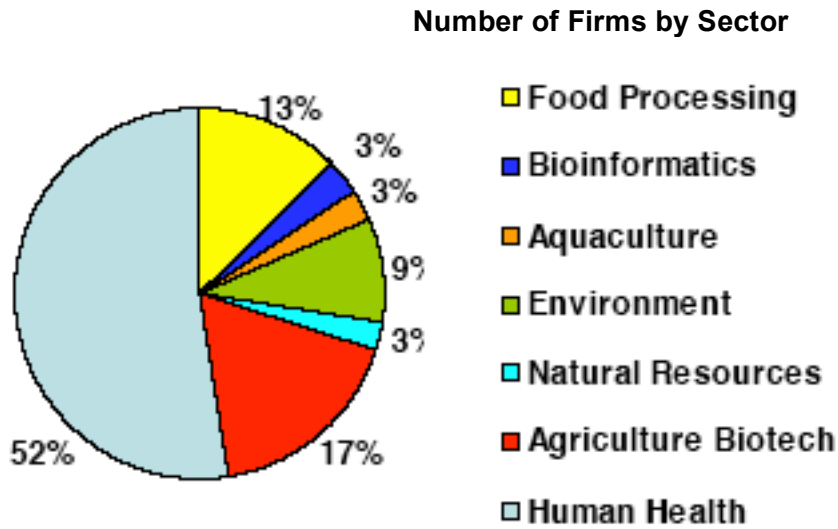
There is no single or simple description of the biotechnology industry. It is not an industry in the usual sense. Biotechnology, as its name implies, is an enabling group of technologies that can be applied across a wide variety of industrial and commercial processes. It has important applications in industries related to human health, such as diagnostics and pharmaceuticals, as well as to agriculture and food, forestry, environment and energy. biology and health.

A wide variety of private and public sector players are involved in the biotechnology sector, including companies, governments, research institutes, hospitals, universities and technical colleges. The sector is heavily focused on therapeutics and diagnostics for human health.

Biotechnology in Ontario:

- 3,346 employed (28% of Canada)
- in 101 biotech companies
- \$1,376M in biotech revenues
- employment down 0.5% in 2004

The majority (70-80%) of Ontario's biotechnology employees work in the health care sector.

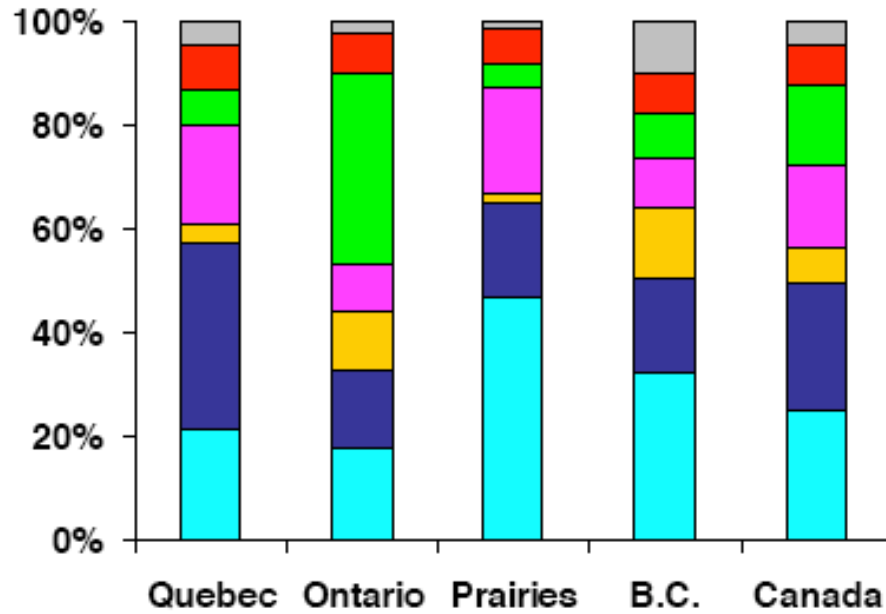


Career paths in biotechnology generally include:

- Sales and marketing
- Quality control assurance
- Administration and regulation
- Clinical research
- Manufacturing
- Research and development

“Skill-intensive” positions (scientific research/direction and technicians) make up the bulk of biotech employment in Canada, with 52% in 1999 and 49% in 2001. Ontario has the largest portion of its workforce in finance and marketing positions, a sign of its growing maturity.

**Employment Distribution in Biotech Firms
in Canada by Type of Position, 2001**

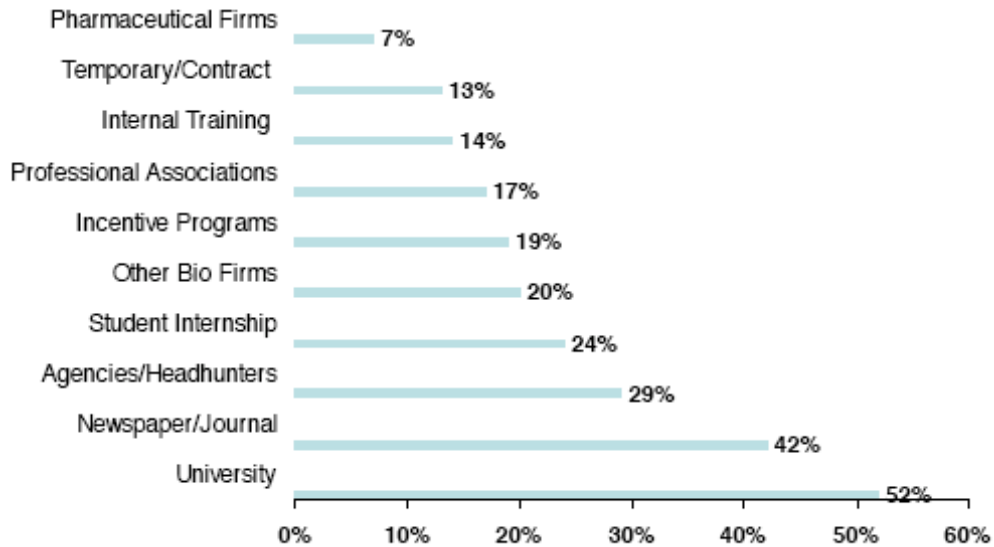


- Scientific Research & Direction
- Technicians
- Regulatory/Clinical
- Production
- Finance/Marketing
- Management
- Other

2.1.2 Biotech Recruitment

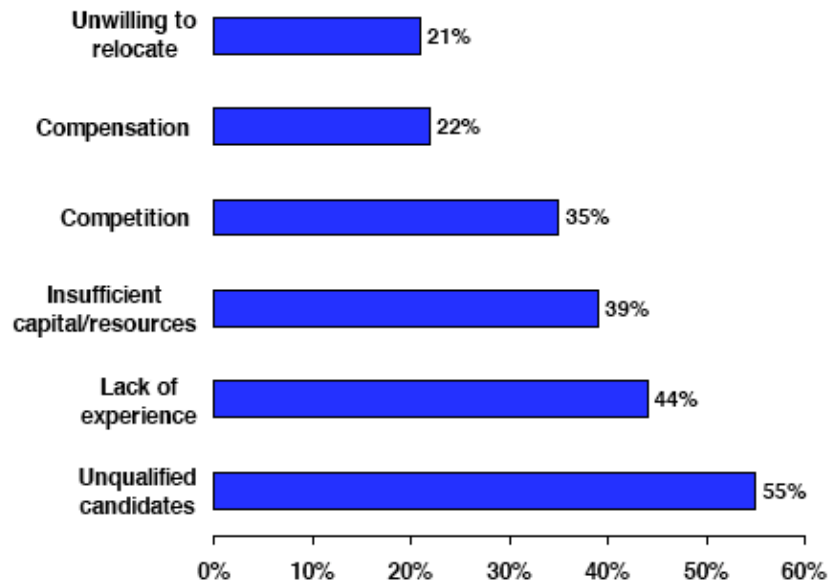
- The top recruitment sources for biotech positions are universities and newspapers/journals.
- 91% of firms in Canada are successful at recruiting biotech employees

Sources of Recruitment For Canadian Biotech Firms, 2001



2.2 Labour Market Prospects

Factors Affecting Hiring for Biotechnology Positions in Canada, 2001



2.2.1 Biotechnology HR Issues And Challenges

(Source: 2004 CBHRS)

The majority of firms in Canadian biotechnology are very small. Technology, financing and basic survival tend to be the issues highest on the corporate agenda.

HR concerns tend to be secondary although firms want access to “job-ready” employees who can grow and adapt with the company.

In addition:

- qualified managers,
- intellectual property experts and
- regulatory affairs specialists

were all deemed to be in short supply.

Management Talent – The Canadian biotechnology industry needs experienced managers that can guide company growth and move products through the commercialization process to the marketplace. Managers of smaller firms need a mix of skills. They have to manage technology, find funding and develop alliances and deals that are required to achieve commercial success. In addition, they need all the skills required to run what is initially a small business that will likely grow rapidly. Companies have had to import individuals with the required skills and expertise mix from the larger pool in the US. This shortage of qualified people is impacting the growth of Canadian biotechnology.

Attracting Top Talent – When companies recruit from abroad they encounter an expensive and uncertain recruitment process, high salary levels, immigration requirements, taxation issues and the fundamental problem of finding qualified people. Governments, hospitals and universities view themselves as less competitive than the industry as a whole in attracting personnel. This may be due to a lack of financial resources to pay competitive salaries and to purchase leading-edge equipment and advanced laboratory technology that attracts top R & D talent. However, working for these organizations has advantages beyond compensation. For example, hospitals, institutes and governments provide greater employment security than can be offered in smaller companies.

Employee Training and Development – Information collected for the study shows that Canada’s educational institutions are now more responsive to the needs of the biotechnology sector than in the past. For example, several universities now offer undergraduate courses and graduate programs oriented towards biotechnology. However, in keeping with the notion that small firms want “job-ready” candidates, educators still need to blend scientific and technical training with basic business skills and related areas such as intellectual property and regulatory affairs. Educational institutions have been successful in tracking emerging industry needs. Despite commendable efforts, firms continue to feel that more could be done in training “job-ready” candidates.

2.2.2 Biotechnology Sector Opportunities

(Source: 2004 CBHRS)

Survey respondents were asked to predict the demand for biotechnology workers in their organization in the next three to five years in three areas:

- Biotechnology research activities
- Product development and production
- Commercialization and marketing

Over half indicated that they believe that the demand for the following workers will be high or very high:

- Senior management;

- Business development and capital financing;
- Research managers;
- Ph.D. staff; and
- Research technicians.

Human health companies rate the need for senior management and regulatory affairs highest whereas the agriculture biotechnology respondents rate technicians and Ph.D. staff highest.

National survey respondents provided information on unfilled full-time biotechnology-related positions the company had, why they were unfilled and where they were targeting recruitment for these positions. Categories and positions proposed included:

- biotechnology
- research (technicians, M.Sc. staff, Ph.D. staff, research managers, other);
- biotechnology product development and production (production or purification scale up, licensing professionals, regulators/clinical affairs, quality control/assurance, informatics, management or supervisors, other);
- and biotechnology commercialization and marketing (business development and capital financing, marketing professionals, sales staff, finance, marketing and sales alliance managers, management, senior management, other).

Reasons For Vacancies

When looking at the reasons why these positions were unfilled, companies were most likely to cite:

- Lack of candidates with required experience;
- Compensation required is too high to match;
- Lack of candidates with both required training and experience; and
- Competition from other sectors

Although half of the interviewees from organizations using emerging technologies said that they are not experiencing a shortage of scientific and technical staff today, all anticipate a shortage in the near future. In particular, as the biotechnology industry matures, some interviewees talked about an impending shortage of skilled senior scientists who will be able to guide their organization towards commercialization. As many areas of emerging technologies (e.g. proteomics, genomics, bioinformatics) are still in relatively early stages of development, the challenge will be to find individuals who can bridge the science and business world to bring these technologies to commercialization.

Interviewees were asked to predict how the competencies for scientists and technical personnel will change as the biotechnology industry evolves. A number noted that there will be a need to expand existing skills in order to keep up with rapidly changing technologies. This will need to be complemented by a more in-depth understanding of the field that they are in, as well as an appreciation of related disciplines. It was noted that science and technology professionals will need to adapt to the business world in order to understand business principles and how they impact on a company's scientific decisions.

Training:

The biotechnology community was viewed as being supportive of non-traditional approaches to training and exposure, such as allowing on-site tours and exposure to hands-on laboratory work. As such, many educational institutions have successfully implemented co-op and internship programs despite potential intellectual property sensitivities.

Providing co-op placements, internships and mentorship opportunities for students was viewed as a valuable role for industry and one that will continue to be key in developing future biotechnology employees.

(ACST):

The “Stepping Up” report found no current evidence of a generalized and persistent shortage of technical skills in the biotech industry. On the whole, Canada’s education and training providers and immigration system appear to be keeping up with the demands of Canadian employers for technically skilled people. Indeed, in some highly specialized and advanced fields of study, Canadian universities are producing more graduates than Canadian firms currently can absorb. Nevertheless they note, that some firms are already incurring difficulties recruiting and retaining the technically skilled workers they need in a number of niche areas. These challenges will grow and become more generalized in the coming years. In biotechnology, due to rapid growth or the requirement for extremely specialized skills, some firms may find it very difficult to fill positions with fully qualified people.

However, based on reports from industry executives, at the moment most firms are coping adequately with these difficulties, which are not inconsistent with the normal ebb and flow of dynamic labour markets.

In sharp contrast with the technical skills picture, but equally critical to the competitive success of Canadian industry, is a persistent shortage of people who combine strong technical abilities with essential skills (e.g. communications and teamwork) and management skills (e.g. cost control and budgeting). In all five sectors, executives reported that finding technically competent people who can work in teams, communicate effectively and apply their technical knowledge to real world business problems, is a significant challenge.

2.2.3 Skill-set Requirements

The industry has a wide range of skill requirements, including entry-level and senior researchers, technicians, engineers, scientists and management, as well as experts in areas as diverse as intellectual property, quality assurance, informatics and marketing. The characteristics of the biotechnology industry, therefore, pose unique HR challenges. The development of emerging technologies requires new skills – often immediately. As many companies move through their life cycle, they require new technical, management and leadership skills not needed at earlier stages. The rapid growth of the industry means that these skills required by companies at mid and later stages of development are in short supply. Similarly, as products move to commercialization, skills are needed in companies and public sector bodies in areas such as regulatory and legal affairs. In short, the competitive, international and rapidly changing nature of this industry is resulting in demand for a wide variety of skills.

Finding talent with the necessary management skills and strategic alliance experience was hindering their firms’ ability to meet corporate objectives (see following table). Another top issue identified as a challenge was attracting people with regulatory skills. The third most frequently cited challenge was attracting people with direct commercial application of research skills.

TABLE 5: FACTORS AFFECTING ACHIEVEMENT OF CORPORATE OBJECTIVES

THE CHALLENGE OF _____ IS HAVING A NEGATIVE IMPACT ON THE ABILITY OF MY COMPANY TO ACHIEVE ITS OBJECTIVES. (N=60)

CHALLENGE	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree	Do Not Know
ATTRACTING PEOPLE WITH MANAGEMENT SKILLS	18%	38%	29%	13%	3%	–
ATTRACTING PEOPLE WITH STRATEGIC ALLIANCE EXPERIENCE	11%	37%	37%	14%	2%	–
ATTRACTING PEOPLE WITH REGULATORY SKILLS	19%	26%	40%	11%	2%	2%
ATTRACTING PEOPLE WITH DIRECT COMMERCIAL APPLICATION OF RESEARCH	13%	32%	36%	13%	–	7%
ATTRACTING PEOPLE WITH MERGER EXPERIENCE	11%	30%	40%	10%	2%	8%
ATTRACTING PEOPLE WITH SCIENTIFIC SKILLS	14%	24%	29%	21%	11%	2%
ACCESSING A QUALIFIED LABOUR SUPPLY	13%	24%	33%	24%	6%	–
ATTRACTING PEOPLE WITH TECHNICAL SKILLS	13%	24%	27%	27%	10%	–
ATTRACTING PEOPLE IN QA/QC	5%	21%	49%	18%	2%	5%
ATTRACTING PEOPLE IN PRODUCTION	6%	18%	52%	11%	2%	11%
ATTRACTING PEOPLE IN INTELLECTUAL PROPERTY	3%	19%	54%	11%	3%	10%
ATTRACTING PEOPLE IN MARKETING	5%	15%	40%	26%	7%	8%
ATTRACTING PEOPLE IN FINANCE	6%	8%	35%	41%	8%	2%

2.2.4 Human Resource Planning for the Future

HR was considered as a top (important or very important) issue by about one-third of respondents. Biotechnology firms, particularly smaller, research-intensive firms face a number of challenges that typically include financing, intellectual property, or development issues – issues likely to demand immediate attention. Given that many biotech firms are operating in “survival” mode, it is not surprising that HR issues are under-rated. HR issues tend to flare up when key staff members leave or when expansion of a critical corporate function is required. At that point, specific HR challenges and needs arise and more attention is given to them. Based on the overall study, all respondents agreed that the performance of their organization depends on the actual performance of employees; thus HR remains a substantial core issue.

Emerging technology firms, which tend to be smaller in size, indicated that senior management have the prime responsibility for recruiting, retaining and developing people. It was also indicated that senior management plays a lead role in identifying key talent internally and developing succession plans. An alternative approach noted was contracting with a qualified HR professional to develop specific policies and procedures and to develop and/or improve the company’s HR framework. A number of emerging technology interviewees indicated that their organizations were responding to the anticipated future HR challenges by developing targeted strategies, while others have taken a “wait and see” attitude.

2.3 Links

- Biotechnology Human Resource Council <http://www.bhrc.ca/>
- Health Products and Food Branch http://www.hc-sc.gc.ca/hpfb-dgpsa/index_e.html
- Strategis, Life Science Gateway <http://strategis.ic.gc.ca/epic/internet/inlsg-pdsv.nsf/en/Home>
- Bio Ontario <http://www.bioontario.ca/>
- Canadian Health Services Research Foundation Listing of Research Centres
- Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/193.html>
- CanBiotech Biotech Portal and B2B Marketplace <http://www.canbiotech.com/>

3.0 Details on Various Occupations

- 3.1 Researcher
 - Clinical Researcher (*see separate information sheet #20*)
- 3.2 Microbiologist and Immunologist
- 3.3 Biotechnology Technologists
- 3.4 Medical Information Associate
- 3.5 Regulatory Affairs Associate
- 3.6 Biostatistician
- 3.7 Sales Representative

3.1 Researcher - R & D

Levels of R&D professionals

Source: <http://jnpharmarnd.com/careers/scladder.html#ResearchA>

- Distinguished Research Fellow, Senior Research Fellow, Research Fellow Research Fellowships
- Principal Scientist
- Senior Scientist
- Scientist
- Senior Associate Scientist
- Associate Scientist
- Research Associate
- Research Assistant

(i) Principal Scientist

Doctorate normally required, with the experience and demonstrated ability at the Senior Scientist level to warrant consideration for the Principal Scientist level. Plans discovery and development programs and originates, designs and/or directs investigations in areas assigned to the laboratory. Actively interacts with the internal and external scientific community to maintain a state-of-the-art knowledge. Participates in supervisory process, including training and evaluating associate staff, as well as coordinating their work.

Candidates for promotion to any of the three Research Fellow positions, Research Fellow, Senior Research Fellow and Distinguished Research Fellow, must have a record of significant scientific achievement and value-added contributions to the company. An important factor is the candidate's involvement in scientific activities that contribute to the future success of the business. Candidates can also have a commensurate portfolio of professional experience, scientific achievements, and value-added contributions in positions outside of the company.

(ii) Senior Scientist

Doctorate normally required, with the experience and demonstrated ability at the Scientist level to warrant consideration for the Senior Scientist level. Conducts research directed toward the discovery and/or development of therapeutic agents with a project emphasis. Ensures quality conduct of projects, including design, data summary and interpretation, report and manuscript preparation and review and adherence to applicable regulations. Participates and consults with the internal and external scientific community to maintain a state-of-the-art knowledge for application to successful conduct or experiments and projects. Will probably participate in the supervisory process, including training and evaluating associate staff, as well as coordinating their work.

Generally, candidates considered for Principal Scientist must make recognized contributions to the research and development efforts of the company. They must demonstrate a broad knowledge of state-of-the-art scientific principles and theory. Candidates must also be able to serve as a consultant, in or out of the business, to serve as a spokesperson on research and development issues, and to advise management. They must be able to direct the development of patent applications. Candidates can also have an equivalent portfolio of achievements in positions outside of the company.

(iii) Scientist

Doctorate with no relevant industrial experience ("entry level") or master's or bachelor's degree with experience that provides a base of knowledge and ability commensurate with that of a doctorate. The Scientist conducts research directed toward the discovery and/or development of therapeutic agents. Ensures quality conduct of experiments, including experimental design, data summary and interpretation, report and manuscript preparation and review and adherence to applicable regulations. Participates and consults with the internal and external scientific community to maintain a state-of-the-art knowledge for application to successful conduct of experiments and projects. Might participate in the supervisory process.

To be considered for promotion to the next level, Senior Scientist, candidates generally must be able to originate, design and make recommendations to initiate, change or terminate discovery and development projects.

(iv) Senior Associate Scientist

Master's or bachelor's degree with experience at the Associate Scientist level or equivalent external experience. Working under minimal supervision, conducts research and contributes to the origination or direction of experiments and new laboratory methodologies. Prioritizes tasks according to broad project goals. Actively involved with scientific consultants and collaborators from outside the company.

Candidates for promotion to Scientist generally must demonstrate a strong ability to organize, plan and solve research problems. They must demonstrate leadership and ability to develop subordinates to perform these tasks. In addition, they must possess interpersonal skills to influence colleagues effectively. Candidates must also be able to deliver effective oral and written communications.

(v) Associate Scientist

Master's or bachelor's degree with experience at the Research Associate level or equivalent external experience. Under general supervision, the Associate Scientist independently solves routine problems and develops solutions in more unusual situations. Recommends modifications to methodology, understands the impact of these modifications on the broader research area, schedules experiments in the lab and provides guidance to individuals in more junior positions. Must be able to interact with employees outside of his or her immediate work group.

Candidates for advancement to Senior Associate Scientist, the next level, generally must be able to perform research and contribute to the origination or development of projects. They must be able to review, analyze and interpret data and prepare reports.

(vi) Research Associate

Master's degree with no relevant industrial experience ("entry level") or bachelor's degree with equivalent experience that provides a base of knowledge and ability commensurate with a master's degree. Conducts research in assigned areas, under general supervision, using established methodology. Develops methodology under direct supervision. Performs limited literature

searches, maintains and operates all laboratory equipment and summarizes and interprets raw data. Individuals at this level should be developing skills by contributing to the origination or to the development of projects, preparing basic reports and increasing their application of theoretical knowledge.

Candidates for promotion to the next level, Associate Scientist, generally must be able to perform research and contribute to the start or development of experiments. In order to be promoted, candidates must be competent to review, analyze and interpret research data and to prepare technical reports.

(vii) Research Assistant

Bachelor's degree with no relevant industrial experience ("entry level") or equivalent experience that provides a base of knowledge and ability commensurate with a bachelor's degree. The Research Assistant conducts research in assigned areas using established methodology. Records, stores and summarizes information and data. Prepares technical reports. Develops laboratory skills and familiarity with equipment to summarize raw data. Identifies and recommends solutions to routine problems.

Candidates for advancement to the next level, Research Associate, generally must be able to demonstrate research and development techniques, analyze and interpret research data, identify routine problems and recommend solutions. To be promoted, candidates must also be able to prepare technical reports.

Skills/Qualities of Researchers

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge
- Specialized computer software: statistical analysis

Communication

- Strong oral and written communication skills

Other

- Observation, analysis and documentation skills
- Able to prepare technical reports, summaries, protocols, and quantitative analyses
- Creative, imaginative, hardworking individual who enjoys interacting with other scientists
- Logical, persistent
- Cooperative and able to work well with others
- Able to handle multiple tasks and meet deadlines
- Strong organizational and presentation skills
- Good interpersonal skills

Average Salary of Researchers

Source: http://www.globalnetworkassociates.com/why_ca13.htm#

\$47,197/ year to \$72,158/ year (\$24.20/hour to \$37.00/hour)

Salaries depend on factors such as: occupation, responsibilities, experience, seniority, size of company, size of city, etc.

3.2 Microbiologists and Immunologists

Role

Source: <http://jobfutures.ca/noc/212p1.shtml>

Microbiologists and cell and molecular biologists research such areas as bacteria, fungi, viruses, tissues, cells, pharmaceuticals, and plant/animal toxins.

Microbiologists study the biochemical, physiological and genetic aspects of micro-organisms, and how micro-organisms interact. In general, this involves:

- Working in or creating aseptic conditions
- Studying human diseases caused by micro-organisms
- Conducting experiments to isolate and make cultures of specific micro-organisms under controlled conditions
- Analyzing nucleic acids, proteins and other substances produced by micro-organisms
- Performing tests on water, food and the environment to detect harmful micro-organisms and control sources of pollution and contamination
- Observing, identifying and classifying micro-organisms
- Isolating micro-organisms involved in breaking down pollutants
- Developing modified microbes for use in the production of specialty biologicals or for gene transfer

Medical microbiologists may also help scientists and physicians in the diagnosis, prevention and treatment of infections in animals and humans by investigating:

- How organisms cause disease and their role in disease processes
- Factors contributing to the occurrence of disease in a population and how epidemics can be controlled

Work in microbiology is often interdisciplinary so microbiologists may work closely with chemists, biochemists, geneticists, pathologists, physicians, environmental scientists, engineers, veterinarians or geologists.

Microbiologists may specialize in fields such as:

- Bacteriology, conducting research into the characteristics of bacteria or a particular aspect of bacteriology such as public health bacteriology
- Pharmaceutical bacteriology, hospital (clinical) bacteriology, environmental microbiology or biotechnology
- Immunology, studying immune reactions in humans or animals
- Molecular microbiology, investigating how bacteria or viruses function at the molecular level
- Mycology, studying fungi
- Virology, studying viruses
- Parasitology, studying parasites.

Microbiologists and cell and molecular biologists perform some or all of the following duties:

- Conduct research into the structure, function, ecology, biotechnology and genetics of micro-organisms, including bacteria, fungi, protozoans, and algae
- Conduct research into the structure and functioning of human, animal and plant tissues and cells
- Conduct studies into the identification, effects and control of human, plant and animal pathogens and toxins
- Conduct clinical or laboratory studies to test, evaluate and screen drugs and pharmaceuticals

- Conduct molecular or biochemical studies and experiments into genetic expression, gene manipulation and recombinant DNA technology
- May supervise biological technologists, technicians and other scientists

Educational Requirements

Source: <http://www1.on.hrdc-drhc.gc.ca/ojf/ojf.jsp?lang=e§ion=Profile&noc=2121>

- A bachelor's degree in biology or in a related discipline is required for biologists
- A master's or doctorate degree in biology or a related discipline is required for employment as a research scientist in biology
- Postdoctoral research experience is usually required before employment in academic departments or research institutions
- Biologists and related scientists may specialize in botany, zoology, ecology, and marine biology, or at the cellular and molecular level in fields such as genetics, immunology, pharmacology, toxicology, physiology, pathology, bacteriology and virology

Skills/Qualities

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge
- Specialized computer skills in analyzing data: statistical analysis software
- Microbiologists use a variety of specialized equipment such as gas chromatographs and high pressure liquid chromatographs, electrophoresis units, thermocyclers, fluorescence activated cell sorters and phosphoimagers.

Communication

- Able to communicate clearly, both orally and in writing

Other

Source: <http://mb.jobfutures.org/profiles/profile.cfm?noc=2121&lang=en&site=graphic>

Biology professionals require technical skills related to research and/or application of science.

- Ability to theorize, plan and conduct experiments
- Patience and an interest in the nature of life
- Objective and able to concentrate on details
- Analytical, problem-solving and decision-making skills
- Able to work independently or as part of a team
- an inquiring mind and a wide interest in natural phenomena
- Manual dexterity (for transferring micro-organisms from one culture medium to another without contaminating samples, and for mounting and staining specimens)
- Scientists are required to stay up-to-date on regulations and legislation and on technological changes
- In business settings, skills in budgeting, marketing and project management may be required
- They should enjoy synthesizing information to find innovative solutions to problems, working with instruments and equipment at tasks which require precision, and directing the work of others.

Typical Employers

Source: <http://www1.on.hrdc-drhc.gc.ca/ojf/ojf.jsp?lang=e§ion=Profile&noc=2121>

- Hospitals
- Federal and provincial governments
- Medical laboratories
- Universities
- Pharmaceutical companies
- Environmental consulting companies

- Service firms to agriculture

Salary Range

Source: <http://www1.on.hrdc-drhc.gc.ca/ojf/ojf.jsp?lang=e§ion=Profile&noc=2121>

\$49,886/ year (average) \$25.58/hour (average)

Salaries depend on factors such as occupation, experience, seniority, size of company, size of city, etc.

Links:

Canadian College of Microbiologists <http://www.ccm.ca/>

3.3 Biotechnology Technologists

- Not a regulated profession in Ontario
- Certification available: Ontario Association of Certified Engineering Technicians and Technologists (OACETT)

Role

Source:

http://www.alis.gov.ab.ca/occinfo/Content/RequestAction.asp?aspAction=GetHTMLProfile&format=html&occPro_ID=71001560

There are a number of developing specialties in the field of biotechnology, including the following:

- **biochemical engineering** - the development of scale-up processes (for example, for fermentation) to produce larger quantities of a substance at one time
- **biochemical production** - the production of chemicals, hormones and other substances in high volumes
- **down-stream processing** - the separation and purification of chemicals and biological products produced by organisms
- **forensic sciences** - the use of deoxyribonucleic acid (DNA) for identification purposes (for example, in criminal cases, paternity suits, mass disasters)
- **genetic engineering** - the transfer of genes from one species to another (in particular, the application of recombinant DNA in producing new substances) or the improvement of genetic properties of plants and animals
- **human cell culture** - the production of antibodies and other useful biological substances
- **industrial microbiology** - the selection and improvement of genetic characteristics for the production of chemical products
- **plant cell culture** - the production of hormones or chemicals by plant cells and the modification of plant cells to improve plants (including plant genetic engineering)

Source: <https://myplace.durhamcollege.ca/durham/profile/progview.jsp?programID=52>

A Biotechnologist is a scientist who uses biology, microbiology, genetics, biochemistry, computer science and engineering to modify or produce new commercial products from living organisms or their components to improve foods, pharmaceuticals, plants, animals, health, and the environment. For example biotechnologists have developed disease resistant plants, biological waste treatment, genetically modified foods and new vaccines.

Educational Requirements

- 2 –3 year Biotechnology Technologist training programs are also available at several Ontario Colleges including Seneca, Mohawk, Algonquin and Canadore Colleges etc. Programs provide students with a solid foundation in biology, biochemistry, microbiology, analytical chemistry, chromatography, spectroscopy, computers, communication skills and

advanced laboratory skills relevant to the biotechnology industry. Students also develop a clear understanding of regulatory affairs and ethical implications of this industry and its influence on society.

Source:

http://www.alis.gov.ab.ca/occinfo/Content/RequestAction.asp?aspAction=GetHTMLProfile&format=html&occPro_ID=71001560

- There is more than one education route to becoming a biotechnologist because biotechnology involves the use of principles from many disciplines. Generally, a bachelor of science degree in genetics, microbiology or biochemistry is necessary to work as a biotechnologist performing technical functions.
- A master's or doctoral degree is required to work in high level technical positions.
- To lead research projects or teach at the post-secondary level, a PhD is usually required.

Skills/Qualities

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge
- Specialized software: data analysis

Communication

- Able to express yourself clearly in oral and written language

Other

- Familiar with scientific methods and experimental techniques, in accordance with accepted principles of quality assurance and manufacturing
- Understanding of regulatory affairs and ethical implications of the biotechnology industry and its influence on society
- Advanced laboratory skills
- Adaptable, open to new ideas
- Possess good analytical judgment
- Able to work under pressure
- Pay close attention to detail
- Curiosity and imagination
- Persistence and a willingness to work long hours
- Willingness to do the reading required to keep abreast of new developments and discoveries
- They should enjoy synthesizing information and finding innovative solutions to problems, working with equipment and instruments at tasks which require precision, and coordinating and supervising the work of others

For further detail on expectations, see the Ministry of Training Colleges and Universities Biotechnology Technologist Program Standards

<http://www.edu.gov.on.ca/eng/general/college/progstan/techno/BioTecno.html>

Typical Employers

- Research is carried out in research laboratories of university, hospital, government institutes and law enforcement forensic laboratories
- Also in the research and development areas of the biotechnology and pharmaceutical industries, food processing industries, agricultural product industries, companies involved in plant or livestock genetic engineering, or in environmental engineering companies

Salary Range

Source:

http://www.alis.gov.ab.ca/occinfo/Content/RequestAction.asp?aspAction=GetHTMLProfile&format=html&occPro_ID=71001560

\$58,300/ year \$29.89/ hour (average)

Salaries depend on factors such as occupation, experience, seniority, size of company, size of city, etc.

3.4 Medical Information Associate (MIA)

- Not a regulated profession in Ontario

Role

The Medical Information Associate provides medical information on company products to customers including health care professionals, corporate partners, third party payers, and patients to ensure that the products are used in a safe and effective manner

The MIA acts as a clinical resource and support for departments such as Sales, Marketing, Customer Response Centre, Sales Training, R&D (Regulatory, Product Safety, QA/QC, Clinical Research), Translation, Legal, and Communications.

Typical job functions may include:

Manage Scientific/Medical Information Resources

- Update/implement related procedures/processes
- Ensure products and related therapeutic area information/publications database is up-to-date
- Develop and update Standard letters database
- Ensure maintenance/enhancement of resources/tools such as MI Lotus Notes Library, customer information database, dialog, micromedex

Manage calls/requests regarding pharma products and therapeutic areas from internal and external customers

- Update/implement related procedures
- Handle calls for medical/scientific information on related products and related therapeutic areas
- Stay current with medical information and analyze information in order to provide accurate and precise information
- Ensure accuracy and effectiveness of customer information database in order to develop analytical reports

Review promotional materials

- Collaborate with marketing to develop new promotional materials
- Ensure information is accurate and supportable (analysis of scientific references for appropriateness of their use in promotional pieces)

Manage Medical writing projects

- Develop bullet brief in collaboration with Marketing and Sales Training
- Develop medical/scientific information packages on various subjects

Educational Requirements

- Bachelor of Science degree in Pharmacy, Medicine, or Nursing

- Often requires 1-3 years experience in the provision of drug information within pharmacy or pharmaceutical industry setting, or equivalent experience

Skills/Qualities

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge
- Proficient in the use of online databases (i.e., PubMed)
- Knowledge of computer software to organize and maintain databases of medical information
- Ensure maintenance/enhancement of resources/tools such as MI Lotus Notes Library, customer information database, dialog, micromedex etc.

Communication

- Excellent oral and written communication skills
- May require bilingual English and French

Other

- Strong customer-focus
- Outstanding interpersonal skills
- Team-focused; works effectively with other members of the organization to establish relationships and follow through on priorities
- Familiarity with Departmental Operation plans
- Understand industry practices relating to medical information and pharmacovigilance
- Understand Local and International Regulations on reporting adverse drug reactions for compliance with government regulations
- Capable of researching market competitors and content of their labeling

Typical Employers

- Pharmaceutical, biotechnology and medical device companies

Salary Range

\$55,000 - \$80,000/ year

\$28.20/ hour to \$41.02/ hour

Salaries depend on factors such as occupation, experience, seniority, size of company, size of city, etc.

3.5 Regulatory Affairs Associate

- Not a regulated profession in Ontario

Role

- Formulate registration strategies for rapid approval of products with optimal labeling
- Manage the preparation of regulatory submissions
- Manage the preparation, submission and rapid approval of Clinical Trial Applications
- Ensure regulatory and corporate compliance for assigned products
- Maintain regular contact with global functional groups regarding specific product related issues
- Liaise with Health Protection Branch (HPB) contacts on assigned submission and product/project related issues
- Review and approve advertising/promotional materials relating to assigned products
- Recommend changes for labeling, manufacturing and marketing for regulatory compliance
- Understand new product and process development and current regulatory issues in Canada and abroad

Educational Requirements

- Usual requirement is a B.Sc. minimum in relevant scientific field (i.e., pharmacology, toxicology, chemistry etc.) plus a post-graduate education certificate in regulatory affairs
- 1 – 3 years regulatory experience in an industry or government setting often requested as well
- 1 year postgraduate programs are available through Seneca, George Brown and Humber colleges
- Programs provide graduates with the specialized knowledge required to help biotechnology, medical device and pharmaceutical companies manage regulatory processes. They gain knowledge of the Canadian health care system, health care legislation, procedures and practices for regulating the development, manufacture, quality assurance and marketing of health care products. An industry internship component provides the opportunity for students to apply and integrate their knowledge in a real world work setting.

Skills/Qualities

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge

Communication

- Excellent oral and written communication skills

Other

- Solid understanding of product development including pharmacology, toxicology, clinical studies, chemistry and manufacturing, controls (GMP) as well as product commercialization and post-launch compliance
- Knowledge and understanding of the Food and Drug Act and Regulations
- Familiar with key international regulations and guidelines
- Excellent presentation skills
- Good creative thinking and research skills
- Good technical writing skills and the ability to review and critique safety, efficacy, and quality
- Strong customer focus
- Strong interpersonal skills with respect to relationship building and teamwork
- Ability to manage multiple projects and priorities effectively
- Work well under pressure
- Strong negotiation and problem solving skills, excellent planning and organizational skills, a strong attention to detail, and the ability to work independently and actively participate as a team member

Typical Employers

Pharmaceutical, biotechnology and medical device industries

Salary Range

Source: <http://www.nextsteps.org/steps/jul02/labour.htm>

\$62,000 year (average)

\$31.79/ hour (average)

Salaries depend on factors such as occupation, experience, seniority, size of company, size of city, etc.

3.6 Biostatistician

- Not a regulated profession in Ontario

Role

Determining the cause of disease, the progression of disease, and the effectiveness of medical treatments and health-related programs requires both appropriate and increasingly sophisticated statistical analysis of available clinical, epidemiological, and public health data.

Biostatistics is an interdisciplinary sub discipline of both statistics and epidemiology that is focused on the application and development of statistical and mathematical methods to the design and analysis of health research and biomedical studies and to the planning and evaluation of health services programs.

Emphasis is placed on statistical theory and methods, epidemiological theory and methods, and data processing and health-related computation.

Source: http://www.stats.uwaterloo.ca/Stats_Dept/research/biostatistics.shtml

- Biostatistical research is typically directed at the development of statistical methods with a view to applications in the biological and medical sciences.
- Specific areas of biological research in which statisticians often play an important role are varied, including among others agriculture, forestry, ecology, kinesiology, and experimental biology.
- In medical research, statisticians are often involved in the design and analysis of cross-sectional studies with the objective of estimating disease prevalence, cohort studies with the objective of modelling disease progression, and prospective randomized clinical trials in which the objective is to evaluate experimental therapeutic interventions in the prevention or treatment of disease.
- An increasingly important area that involves biostatistics, statistical computing, and stochastic modelling is statistical genetics and molecular biology.
- Biostatisticians can work with a wide variety of people such as biologists, physicians, physiotherapists, veterinary scientists, and epidemiologists.
- Excellent employment opportunities arise in hospitals, pharmaceutical companies, universities, and government agencies.

Educational Requirements

- Biostatisticians require a graduate degree
- Some university programs offer combined epidemiology and biostatistics programs

Skills/Qualities

Technical

- Sophisticated computer user
- Experience with statistical methods and models incorporating a broad range of variable types and traditional and modern statistical approaches and experience manipulating large datasets, computing new variables, performing data management on multiple medical datasets, and using large and complex databases. Must have a demonstrated skill and knowledge of SAS and Excel and a demonstrated knowledge of relational database concepts, programming, and SQL language
- Basic computer skills include word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge

Communication

- Ability to speak and write effectively

Other

- Have ability and a strong interest in science and mathematics
- Have the ability to follow a problem to conclusion
- Have the ability to work with a variety of people
- Have the ability to work with governmental regulations
- Have the ability to think logically, analytically
- Have the ability to exercise patience, flexibility, and a willingness to work in different locations under a variety of conditions
- Must be able to work independently, exercise good judgment, solve problems, organize work and set priorities to meet deadlines
- Ability to interact effectively with a diverse group of people
- Ability to train and instruct others in the usage of the department's software

Typical Employers

Biostatisticians are usually employed in local, provincial/territorial and government health departments, federal agencies, private industry, hospitals, public health laboratories, pharmaceutical companies, universities and research.

Salary Range

Source: http://www.globalnetworkassociates.com/why_ca13.htm

\$46,434/ year (average) \$66,163/ year (high)
\$23.81/ hour (average) \$33.92/ hour (high)

Salaries depend on factors such as occupation, experience, seniority, size of company, size of city, etc.

3.7 Sales Representative

Role

Source:

<http://www.quintiles.com/NR/rdonlyres/evx7oei3k6a6pm2ud27jsbcckeoip3kyg43kjak6ocmxyjiuvqi4ylxu73auc ehf6f3jrqqzj6j4tf/PharmaceuticalSalesInfosheet.pdf>

The pharmaceutical sales representative is responsible for the maintenance and increase of sales of a number of prescription medications in a given territory. This is achieved by visiting health professionals to promote the prescription of their products. While the visit aims to change the doctors prescribing behaviour, it is also an opportunity for the health professional to obtain important information regarding the products.

Responsibility for development of maximum sales of your products within the assigned territory through coverage of key doctors.

- Maintenance of accurate records of customers including objections raised if any, specific requests from the doctor and eventual outcomes of the meeting with the doctor
- Ensure timely submission of weekly reports. Reports include record of doctors visited within the territory and other promotional activities for the week. Reports usually include a plan for the following week ahead and any competitor information.
- Ensure prompt delivery of information from the field to marketing department or clinical departments
- Maintain and enhance the knowledge of products and competitor products. This

includes the complete knowledge of clinical papers and new developments within the therapeutic area

- Uphold the professional code as a GP Sales Representative in accordance with the Medicines Australia code of conduct

Educational Requirements

Source:

<http://www.quintiles.com/NR/rdonlyres/evx7oei3k6a6pm2ud27jsbcckeoip3kyg43kjak6ocmxyjiuvqi4ylxu73auc ehf6f3jrqqzj6j4tf/PharmaceuticalSalesInfosheet.pdf>

- This can vary from one organization to the next. Many companies seek candidates with a degree, preferably in a science discipline, or qualifications as a Registered Nurse. Other degree qualifications are also highly regarded.
- For some companies, these qualifications are not essential and they prefer to consider candidates with strong selling backgrounds, ideally with “on the road” territory management sales experience.
- Other companies will look for candidates that have both sales experience and degree qualifications.
- Above all, the personal qualities (like those mentioned below) are key drivers to securing a position.

Skills/Qualities

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge

Communication

- Excellent oral and written communication skills
- Excellent listening skills

Other

- Knowledge of medical field an asset
- Sales, negotiation and territory management skills
- Ability to build strong business relationships and to be resourceful
- High level of professionalism, self motivated, driven to achieve
- Integrity, persuasiveness, tenacity and the ability to create impact
- Leadership skills, innovation
- Able to work independently and as part of a team

Typical Employers

- Pharmaceutical, biotechnology and medical device companies

Average Salary

\$40,000/ year plus, sometimes on commission

\$20.51/ hour plus, sometimes a commission

Salaries depend on factors such as occupation, experience, seniority, size of company, size of city, etc

Source:

<http://globeandmail.workopolis.com/servlet/Content/salesadvisor/20050221/20050222?section=SalesAdvisor>

Pharmaceutical sales is one of the most desired careers in sales today due to the high income earning potential and good career prospects. Generally the majority of pharmaceutical and medical equipment sales personnel have a four year degree in a scientific specialty. Many companies and

sales managers state that a college or university degree is the minimum level of qualification a candidate must possess before they consider hiring a candidate for an entry level position. A few sales managers may consider candidates who do not possess a four year degree if they a few years of business-to-business sales experience plus can demonstrate a commitment to continuous learning and professional development. It really depends upon the company and the sales manager and what requirements they have specified in the job profile for candidates to succeed.

4.0 ITPs in the Field

All ITPs have completed university courses in pharmacology and have the knowledge of medications (i.e., drug indications, contraindications, adverse effects, interactions, dosage, mechanism of action and monitoring). Some also have a background in natural medicine that is directly relevant to the nutraceutical industry.

They have the knowledge of medical terminology and possess communication skills and experience with people that are required of professionals in the industry particularly in the areas of medical information support and clinical research.

Many ITPs had research and clinical research experience during their university studies or in jobs. They are familiar with the types of studies, common statistical tests, data sources and statistical analysis. They have the skills to organize, implement and conduct clinical trials.

Source: excerpted and adapted from Leaving the Bedside – The Search for a Non-clinical Medical Career, American Medical Association, 1993 ISBN#: 0-89970-464-6 Available from the American Medical Association.

Physicians in the pharmaceutical Industry are very often specialists with a specialty relevant to the area of drug research (i.e., diabetes medication - internal medicine)

Those with training in clinical pharmacology are sought after since they understand the clinical work.

Other physicians are often administrators, research administrators and organizers who:

- Develop and clinically evaluate new drugs
- Organize clinical studies
- Recruit investigators for the studies
- Write research protocols
- Set up and monitor studies
- Analyze the data from statisticians
- Write reports
- Publish the data

Physicians with a family medicine background are well suited to medical information support positions (regarding drugs already on the market):

- Respond to queries from patients and physicians
- Keep track of post-marketing toxicity surveys

Interfacing with managed-care companies