TECHNOLOGY
WATCH REPORT

Biopharmaceutical production

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Generalitat de Catalunya
Departament d'Empresa i Coneixement
Secretaria d'Universitats i Recerca

Unió Europea
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TECHNOLOGY WATCH REPORT

Biopharmaceutical production

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1
Overview of innovation and tendencies in Biopharmaceutical production

A biopharmaceutical product, also known as a drug of biological origin, is any **pharmaceutical product** produced or extracted from **biological sources** using **biotechnological techniques**.

Biopharmaceuticals include vaccines, blood, blood components, allergens, somatic cells, gene therapies, tissues, recombinant therapeutic proteins and live cells used in cell therapy. Biological products composed of sugars, proteins, nucleic acids or complex combinations of these substances. They may also be cells or living tissues. These products or their derivatives are **isolated from living organisms, for example humans, animals, vegetables, fungi or microbes.**

Therapeutic areas with enormous potential

These products of biological origin may be used for the treatment of a **wide range of related medical disorders**, including oncology and immunomodulators; systemic anti-infectives; dermatology; blood/haemophilia; sensory organs; central nervous system; respiratory system; gastrointestinal; endocrine and musculoskeletal system.

Nevertheless, some therapeutic areas are considered[1] to show enormous potential in biological subsegments, especially monoclonal antibodies and vaccines. The four key subsegments with greatest unsatisfied needs and important acceptability for the majority of regions are **oncology, cardiovascular diseases, diabetes and immunology.**

At the same time, over the next few years **regenerative medicine** is also expected to show growth potential based, very specifically, on the **rare diseases** segment and **niche therapy areas**. The availability of clinical evidence of efficiency of the curing potential of **gene cell therapies** is having strong impact on the world biological market to the extent that the cell therapy market is expected to show a **growth of 20% to surpass the $10 billion** mark by 2021.

Important opportunities for global growth

The biopharmaceutical industry is the largest segment of the world healthcare industry and is **consistently growing close to 15.4% annual**, with sales revenue of around $200 billion. Experts point out that there are three **global growth opportunities for biopharmaceuticals** during the period 2016-2021: biosimilars, bioanalysis services and oncological therapies.

- **Biosimilars**:

  A biosimilar is a biological product equivalent in quality, efficiency and safety to the original biological drug; an exhaustive comparison process demonstrates that the physical-chemical differences between both products have no significant effect on the benefit/risk profile. Once the equivalence has been accredited and authorised, the biosimilar is one more biological drug.

[1] Frost & Sullivan (2017) Global Biologics Market—Companies-to-Action.

With several blockbuster biologics facing patent expiries, the global biosimilars market is expected to show a 31.5% growth in the next 7-8 years to reach **$66 billion in 2025**. The Asia-Pacific market, with more than 300 molecules currently under development, is the most outstanding.

- **Bioanalysis** services:

  The bioanalytical services providing support for the development of biopharmaceuticals in clinical research is gaining significant importance, and the strong penetration of emerging economies in the segment biosimilars global will drive the need for analysers.

  The biopharmaceutical analytical instrumentation market generated a revenue of $1,092 million in 2015 and is expected to grow at a compound annual growth rate of **7.2% to 2022**[2], covering the entire biologic development value chain with solutions such as biomarker testing, immunogenicity testing, toxicology, and pharmacokinetic testing.

- **Oncological therapies**.

  On the other hand, with a majority of cancer treatments relying on chemotherapy, there is an ardent manufacturing requirement of **novel biologic therapies** such as CAR-T cell therapies or recombinant therapies and antibody drug conjugates (ADCs). The development of immunotherapeutic drugs can also be considered an opportunity for the future: these drugs could be especially interesting in the case of lung cancer (Non-Small Cell Lung Cancer: NSCLC) and melanoma.

The production of biopharmaceuticals (or bioprocessing) uses cells or cell components to obtain biopharmaceuticals products. It is possible to use cell lines from mammals, insects, yeasts, bacteria or plants. **Bioprocesses are highly complex** and include a wide range of techniques.

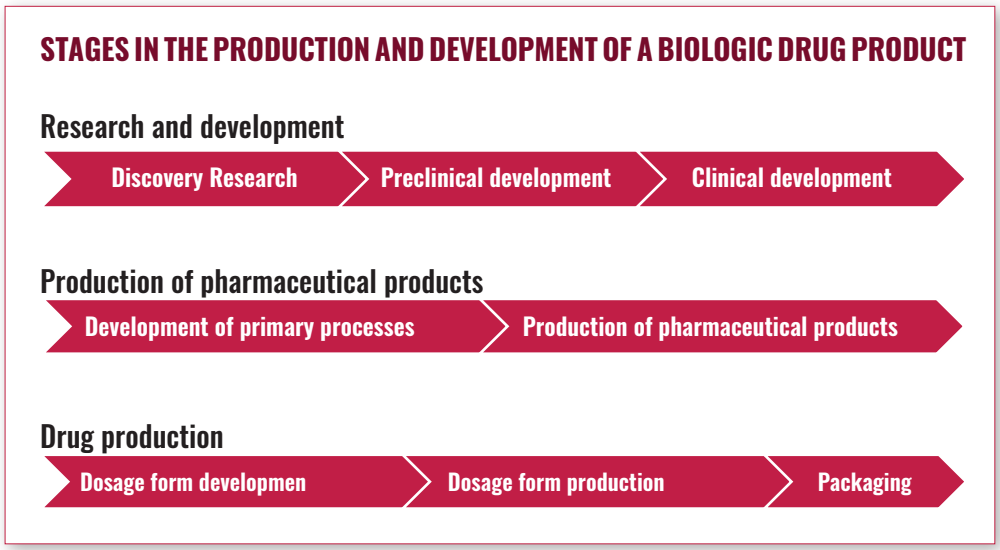
Complex capital-intensive processes

A distinction is made between the products of **mammalian cells** and **microbial cells**, even though the future of the biological product market is to a great extent driven and sustained by the former. The mammalian cell culture market contributes nearly 67% of the sales revenue of the total global biologics manufacturing market and is expected to grow at a significantly higher growth rate than the microbial contract manufacturing market driven by biosimilars, vaccines (flu, pandemic and therapeutic), complex proteins and stem-cell therapies.

The mammalian cell cultures involve the integration of new technologies such as gene editing, new expression cell types and platforms, new single-use bioreactors, and a new chemically defined culture medium which supports cell growth in the absence of ubiquitous proteins.

In all processes that involve cell cultures, the **research and development** of biopharmaceuticals is carried out in **sterile, aseptic conditions and is highly sensitive** to changes in the culture medium. Clinical development, as shown in the diagram below, requires a considerable volume of associated services.

[2] Frost & Sullivan (2017) Global Biopharmaceutical Analytical Instrumentation Market, Forecast to 2022.



Frost & Sullivan (2018) Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022.

The **production of biological drug substances** made up of live cells or tissues composed of sugars, lipids, proteins, or nucleic acids is the phase prior to a **biological drug product** and defines the final dosage form of a biological product, as well as its packaging.

Both phases of manufacture are based on **complex, highly technical processes** where price and the quality of the final product are usually decisive. The manufacture of biopharmaceuticals is knowledge, as well as capital intensive. It is estimated[3] that the investment for building a **new biologics manufacturing plant is typically between $300 and $850 million** and its operating cost greatly exceeds that of chemical drugs.

Even though the highly complex nature of molecules lead to difficulties in manufacturing, more and more **companies invert in molecules during the early stages** of clinical development with the perspective that, if approved, they have the potential of becoming key blockbuster products in a market with forecast growth rates of more than 20%.

As already mentioned, biopharmaceutical companies are located in segments with high unmet needs, as well as high acceptability. But with the growing demand of biologics, companies are now focusing on **gaining in-house expertise** through huge investments as well as **collaborating with external services providers** and **niche players** to attain technology expertise as well as specific therapy expertise.

Collaboration as a competitive imperative

The truth is that in order to compete in this market, **technological implementation is a strategic imperative** closely related to **capturing investment opportunities**. Adoption of newer development and manufacturing techniques including improvements in bioanalytical testing as well as continuous manufacturing processes using disposable bioreactors are improving the efficiency as well as cost effectiveness of production. Owing to the complex methodologies involved in the development of biologics, companies are opting for **integrated business models with digital and medical equipment companies** to support the complex development processes and so acquire technological experience. On the other hand, smaller pharmaceutical companies tend to concentrate on the discovery and development biological substances through **research collaboration with larger pharmaceutical producers**.

[3] Frost & Sullivan (2018) Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022.

In this context of **intensive**, **sophisticated investments** and transition towards models for risk sharing between research workers and pharmaceutical manufacturers, the model imposed is of a **market based on subcontracting research and development** activities on the basis of at least four typical business models:

- **Acquisition:** where Biopharma companies enter niche therapy areas by means of acquiring smaller niche players, thus gaining access to their research products and thereby improving the in-house research pipeline.
- **Outsourcing:** when the growing usage of biologics over other less complex molecules, larger biopharma players are looking to outsource their complex development processes and gain technology expertise.
- **Hybrids:** to meet the growing needs of innovative therapies, biopharma players collaborate with mid-smaller players, thus gaining therapeutic expertise.
- **In-house development:** the growing biologics demand is inducing companies to develop their in-house facilities by means of acquiring newer facilities or advancing existing facilities through investments and technology upgradation.

The **global biologics contract manufacturing market** is expected to grow from $9.3 billion in 2017 to $17 billion in 2022.

This means that the pharmaceutical market uses outsourced supplier services in the form of **Contract Research Organisations (CRO)** and **Contract Manufacturing Organisations (OCM)**, which tend to be segmented into three main categories: active pharmaceutical ingredients (API) manufacturing, fixed dosage form (FDF) manufacturing, and packaging. To attract more clients, certain CMOs are likely to adopt a differentiation strategy that includes repositioning themselves among clients by promoting more services such as formulation improvements, alternate dose formulations, real-time order tracking, and logistics support.

CDMO as a means to improve profitability

Over the last few years the idea has arisen of a single source **integral supplier**, from the development of medicinal products to commercial manufacture, a concept implemented by suppliers known as **contract development and manufacturing organisations (CDMO)**. In this crowded market, an important part of pharmaceutical companies tend to concentrate on basic areas of competition instead of investing in resources, expertise and the technology needed to formulate the end doses of medicinal products, packaging, logistics and apply marketing. The expected shift to **flexible, small-volume manufacturing**, comprising of single-use systems, bioanalytical capabilities, and exploring continuous processing technologies in modular facilities will also drive CDMOs.

The emergence of virtual biotechnology, out-licensing, and risk sharing between pharmaceutical companies and CMOs are disrupting traditional business models. By offering value-added services to pharmaceutical companies, CMOs must redefine themselves as CDMOs and **integrate themselves into the value chain of companies**.

The larger CDMOs are looking to **expand their added value services portfolio** to include regulatory support and bioanalytical services, as well as to **reinforce their geographic presence** and penetrate niche markets, often through the acquisition of small- to mid-sized participants with specific experience in technology, therapeutics, services or the region. One of

Factors for the selection of R+&D & manufacturing suppliers

the key trends in the last few years has been the emergence of CDMOs in emerging markets, particularly in BRIC nations (Brazil, Russia, India and China), in spite of the issues with service and product quality inherent to these markets.

The size, the capacity, the technology, the safety and the confidentiality of a CDMO are **basic requisites** for its selection. Other issues that are both explicitly and implicitly expressed by clients during the selection of a biologic CDMO include:

- therapeutic knowledge
- personnel expertise
- ease of coordination
- project resolution rate
- regulatory track record
- technological services, in-house technology and delivery platforms
- the catalogue of integral solutions
- service costs
- reputation in the sector
- global presence; geographic mobility

The **growth opportunities** of these biopharmaceutical companies are defined by the demand for biological therapies, biosimilars and new generation bioanalytical services.

New tendencies, new opportunities

Experts mention other tendencies in biopharmaceutical production that can also be opportunities in addition to the above:

- **Flexible manufacturing solutions:** Setting up modular facilities requires specialized mobile infrastructure alongside automation controls which may not be easily achievable for most small-to-mid segment pharmaceutical companies.
- **Analytical instrumentation and software:** Equipment manufacturers should recommend different analytical techniques that will support mass spectrometry, to increase customers' productivity. The suppliers of chromatographs (gas chromatographs, liquid and ion chromatographs), molecular analysis spectrometers (infrared IR, ultraviolet-visible UV-Vis and Raman) and analysis spectrometers (atomic absorption, atomic emission and inductively coupled plasma) must adopt integrated systems and technologies such as automation and Laboratory Information Management Systems (LIMS), advanced mass spectrometry, and bioassays, to facilitate sensitivity and accuracy in the analysis of samples. Customers are demanding analysis software that converts the data produced by the instrument into meaningful information for a biopharmaceutical analyst.
- **Disposable bioreactors:** Recent developments across CAR-T Cell therapies have shifted the biologics manufacturing paradigm toward large volume production. The adoption of disposable technologies improves the productivity of traditional batch-fed processes. Advances are being made in both upstream (high-density/intensified and hollow-fibre perfusion) and downstream (continuous chromatography, in-line concentration, tangential flow filtration, and so on). Disposable technologies are

especially designed for the contract manufacture of various products, easy transfer of operations and for occupied installations and light operations. Some companies have developed continuous technology for certain parts of their manufacturing process, and few have announced the use of a fully continuous commercial production.

- **IoT in manufacture:** Therapeutic advances involve new challenges in production planning and logistics where real time data is essential. In this context; there is a tendency to a progressive application of Internet of things solutions supporting the establishment of connected value chains to ensure lower operational costs, while gaining production efficiency of biopharmaceuticals as well as their supply chain, thus favouring product customisation.

Some of the **obstacles to the growth of biopharmaceutical production** are related to in-house packaging, use of the capacity that affects the profitability of CDMOs, the increase in driving times and logistics costs. Furthermore, the increasingly stringent regulations for pharmaceutical manufacturing, particularly mammalian-based manufacturing, are expected to increase the cost of manufacturing, thereby, creating a high entry barrier and making it unsustainable for small companies.

Regulatory requirements with variants.

It is a fact that **regulatory requirements for the approval of biologic drugs will constantly drive the demand** in the biopharmaceutical and analytical instrumentation markets. Global regulatory authorities issue a regional or state license to a biologic drug only if the product, manufacturing process and facilities meet the safety, purity, and efficacy requirements. Biosimilar drug approval regulatory requirements are more severe to ensure the product has the same dosage form, strength, use and side effects as that of the originator. Analytical tools, therefore, are required to profile, assess and record a substance for proof in **regulatory inspections**.

The Committee of Advanced Therapies (CAT) of the European Medicines Agency (EMA)[4] uses the term "advanced therapy medicinal products" (ATMPs) for medicinal products used in humans "based on genes, cells or tissue engineering", including gene therapy medicinal products, somatic cell therapy, tissue engineering and combinations thereof[5]. Despite the availability of a centralized drug approval body, national authorities cause further delays in approvals and launches, because in some jurisdictions, biopharmaceutical products are regulated by **diverse variations of the law**.

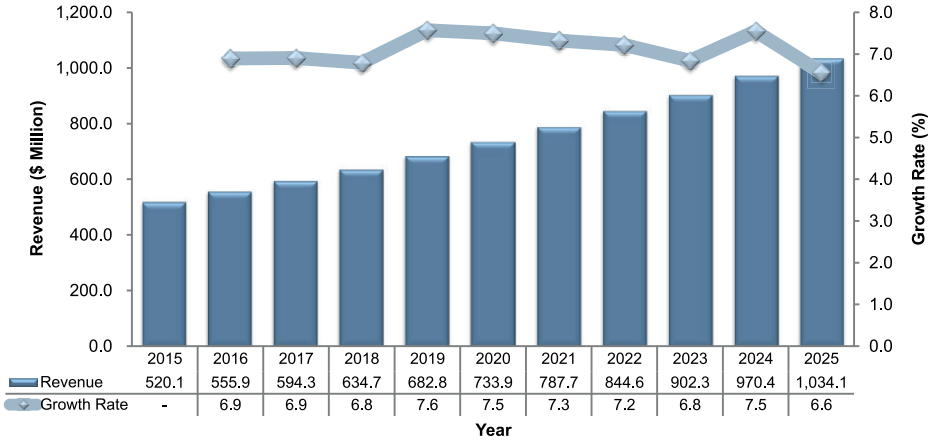
In spite of the obstacles mentioned, a good future for this market is predicted, the **main driving forces** being increased pharmaceutical and biotechnological focus on complex disease areas; tendencies in the control of diseases; the growth of emerging markets, the drop in pharmaceutical patents and the reformulation of existing products.

[4] https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/biologicals/biologicals-active-substance

[5] European Medicines Agency and the European Commission (2019) Biosimilars in the EU. Information guide for healthcare professionals

2
Biopharmaceutical production: Key infographics

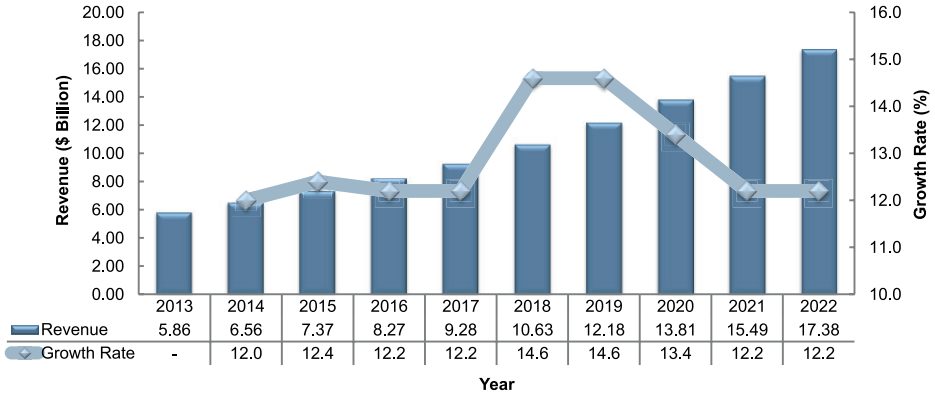
2.1. Biopharmaceuticals Market: Revenue Forecast, Global, 2015–2025



CAGR (2018–2025) = 7.2%

Source: Frost and Sullivan (2019) - Global Analytical Instrumentation Market in Pharmaceuticals, Biopharmaceuticals, and Neutraceuticals, Forecast to 2025 - Growth of Biosimilars and Neutraceuticals will Drive Growth

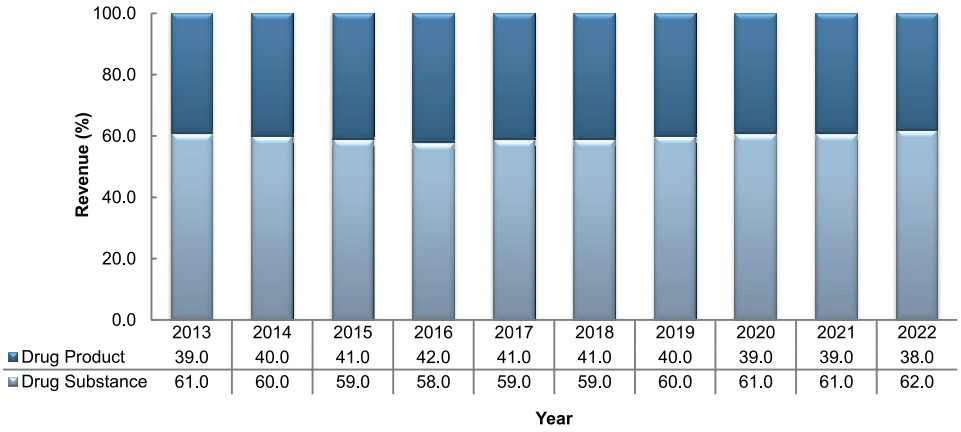
2.2. Total Biologics Contract Development and Manufacturing Organizations Market: sRevenue Forecast, Global, 2013–2022



CAGR 2017–2022 = 13.4%

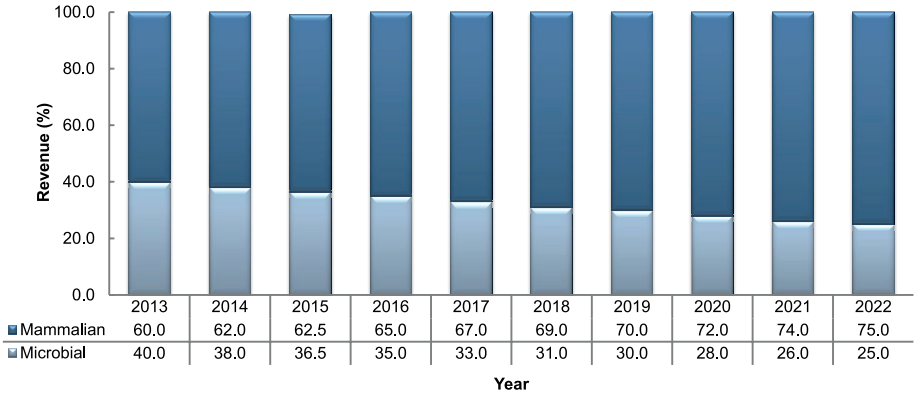
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2.3. Total Biologics Contract Development and Manufacturing Organizations Market: Percent Revenue Forecast by Service Type, Global, 2013–2022



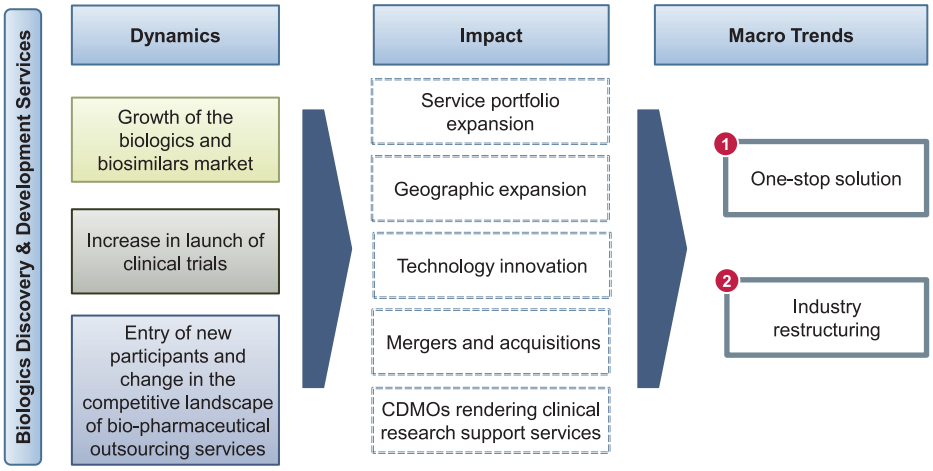
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2.4. Total Biologics Contract Development and Manufacturing Organizations Market: Percent Revenue Forecast by Cell Culture Type, Global



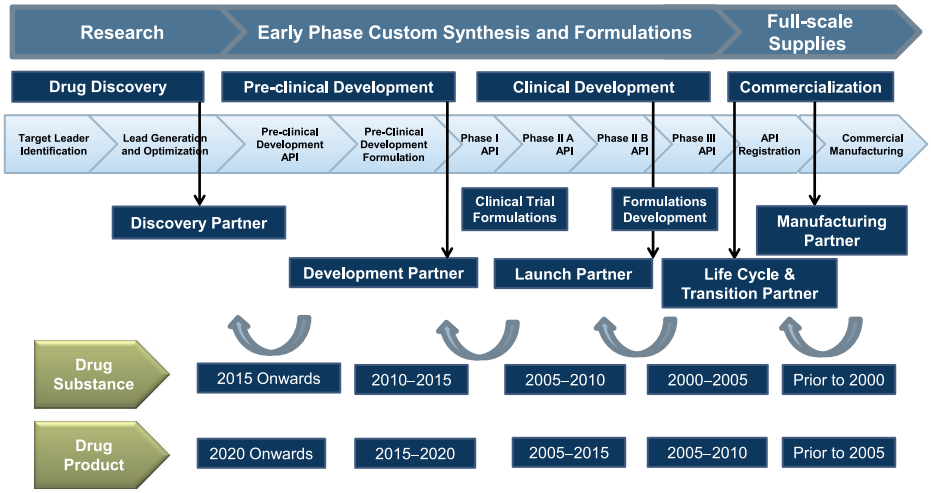
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2.5. Total Biologics Contract Development and Manufacturing Organizations Market: Biologics Development Macro Trends



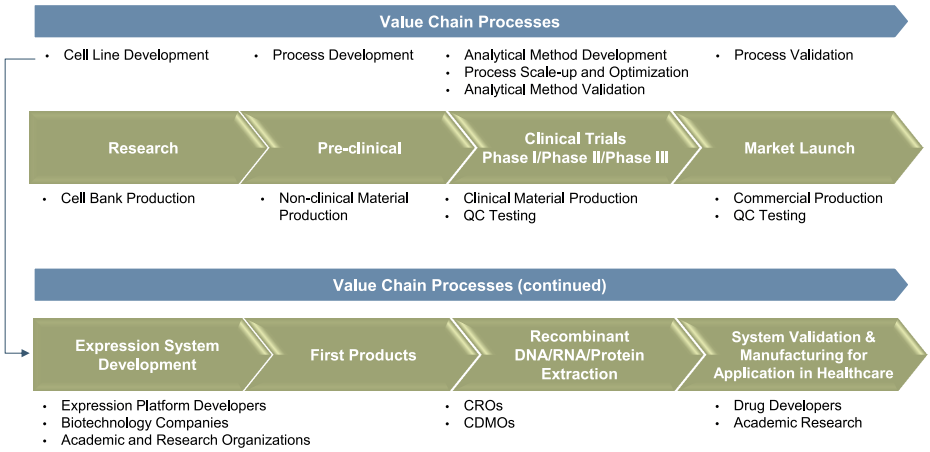
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2.6. Biologics Contract Development and Manufacturing Organizations Market: Emerging Business Models



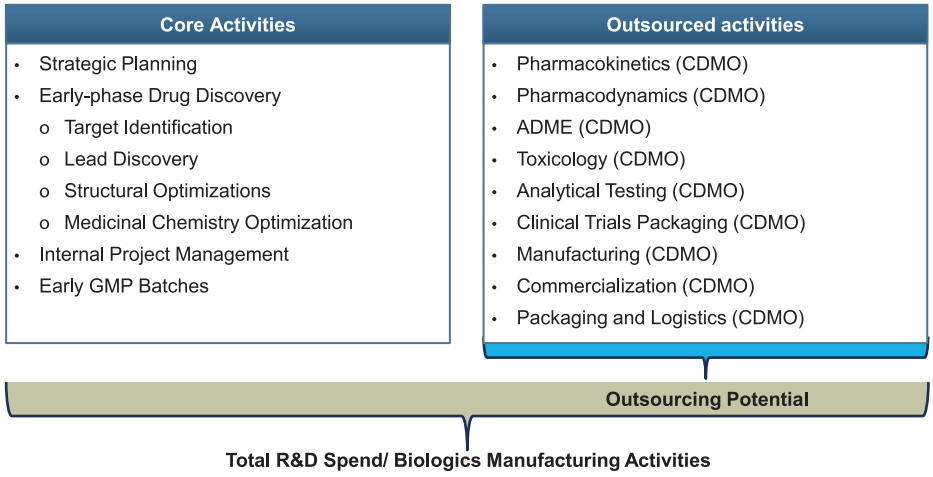
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2.7. Biologics Contract Development and Manufacturing Organizations Market: Value Chain Processes



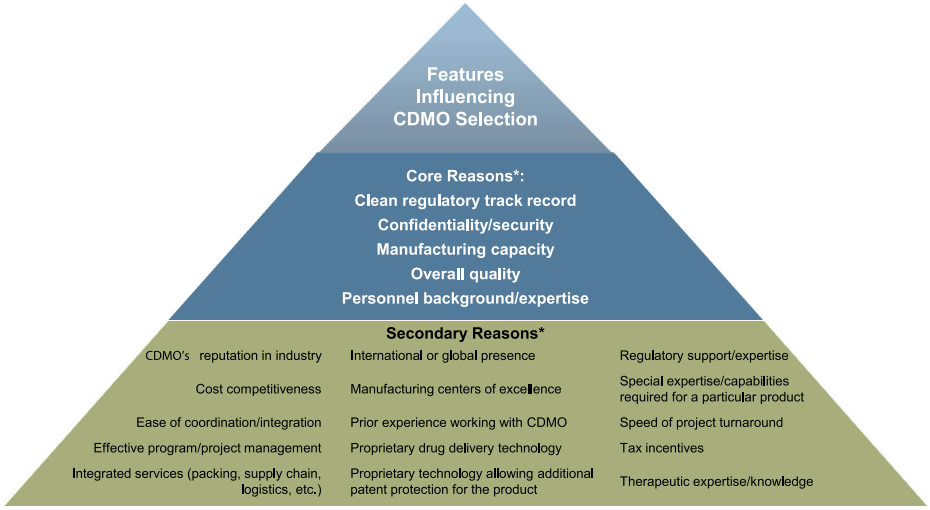
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2. 8. Biologics Contract Development and Manufacturing Organizations Market: Core vs. Outsourced Activities



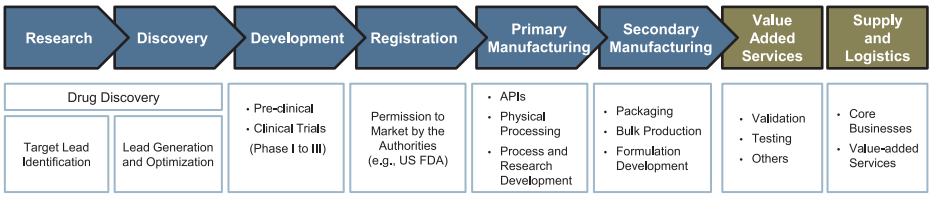
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2. 9. Biologics Contract Development and Manufacturing Organizations Market: Outsourced Reasons



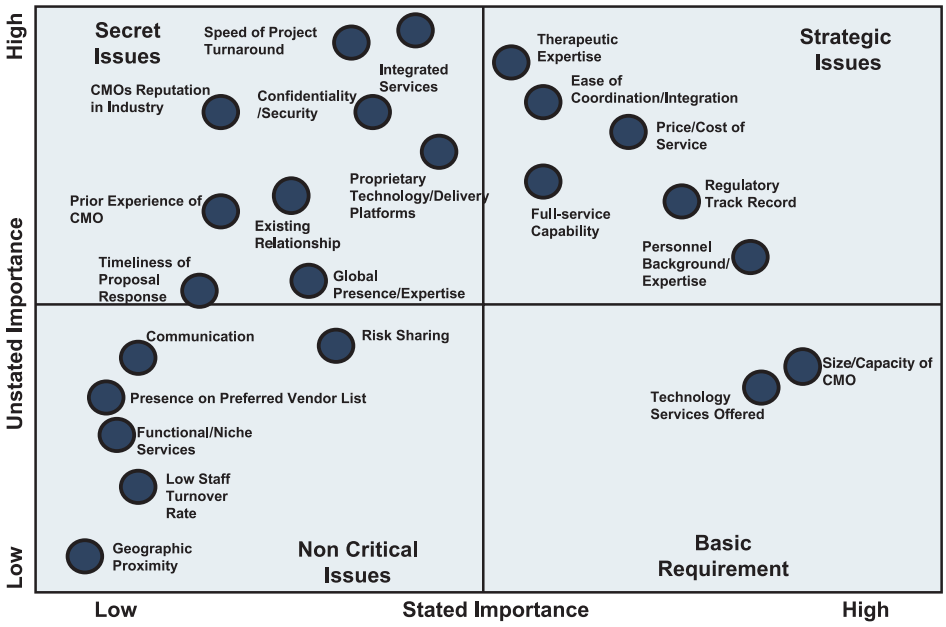
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2. 10. Biologics Contract Development and Manufacturing Organizations Market: Total Contract Outsourcing Market



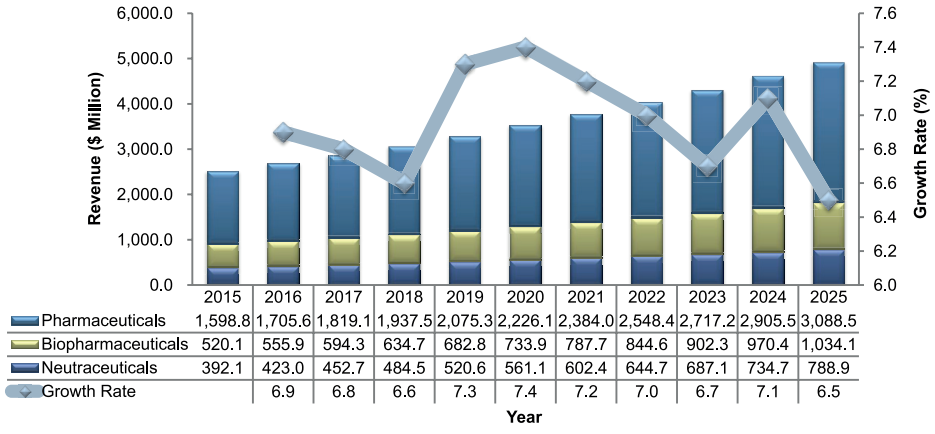
Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2.11. Biologics Contract Development and Manufacturing Organizations Market: Stated vs Unstated Importance of CDMO Selection



Source: Frost and Sullivan (2018) - Global Biologics Contract Development and Manufacturing Organization (CDMO) Market, Forecast to 2022 - Investments in Single Use/Disposable Technologies to Capitalize on Growth Opportunities in High-value Low-volume Biologics

2.12. Analytical Instrumentation Market: Pharmaceuticals, Biopharmaceuticals, and Neutraceuticals: Revenue Forecast by Vertical Market, Global, 2015–2025

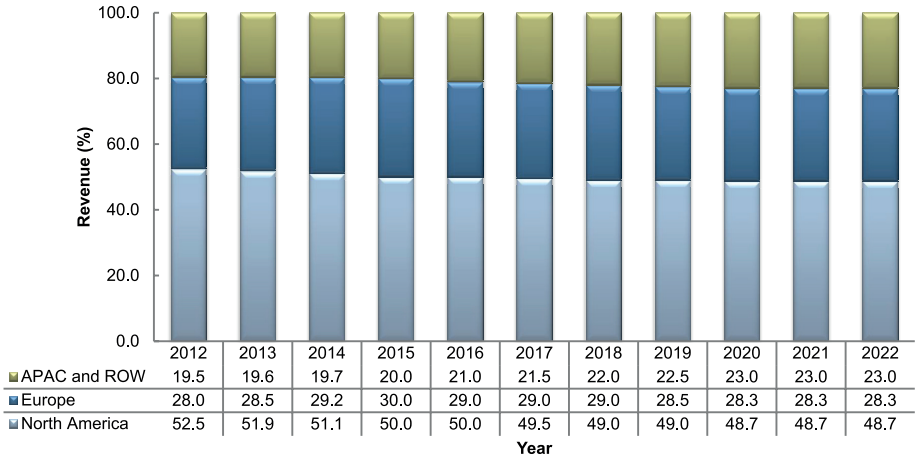


	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Pharmaceuticals	1,598.8	1,705.6	1,819.1	1,937.5	2,075.3	2,226.1	2,384.0	2,548.4	2,717.2	2,905.5	3,088.5
Biopharmaceuticals	520.1	555.9	594.3	634.7	682.8	733.9	787.7	844.6	902.3	970.4	1,034.1
Neutraceuticals	392.1	423.0	452.7	484.5	520.6	561.1	602.4	644.7	687.1	734.7	788.9
Growth Rate		6.9	6.8	6.6	7.3	7.4	7.2	7.0	6.7	7.1	6.5

CAGR (2018–2025) = 7.0%

Source: Frost and Sullivan (2019) - Global Analytical Instrumentation Market in Pharmaceuticals, Biopharmaceuticals, and Neutraceuticals, Forecast to 2025 - Growth of Biosimilars and Neutraceuticals will Drive Growth

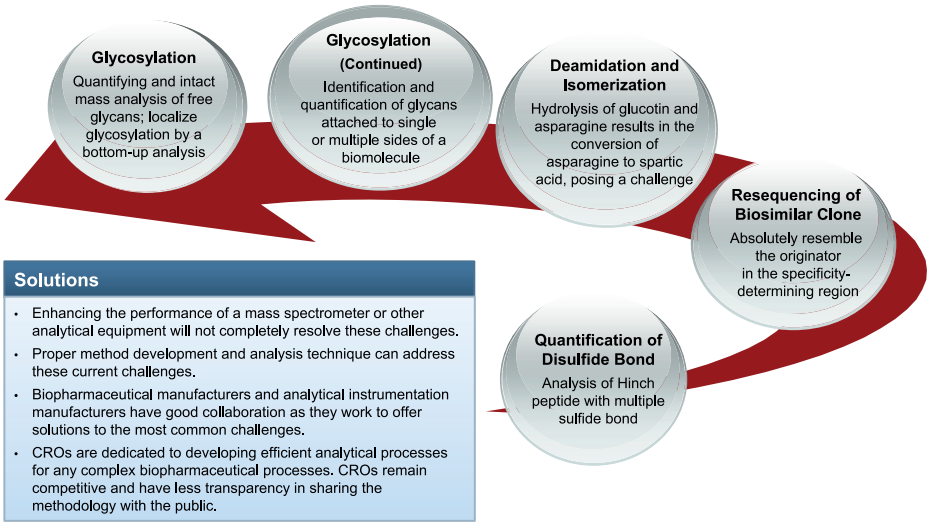
2.13. Biopharmaceutical Analytical Instrumentation Market: Percent Revenue Forecast by Region, Global, 2012–2022



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
APAC and ROW	19.5	19.6	19.7	20.0	21.0	21.5	22.0	22.5	23.0	23.0	23.0
Europe	28.0	28.5	29.2	30.0	29.0	29.0	29.0	28.5	28.3	28.3	28.3
North America	52.5	51.9	51.1	50.0	50.0	49.5	49.0	49.0	48.7	48.7	48.7

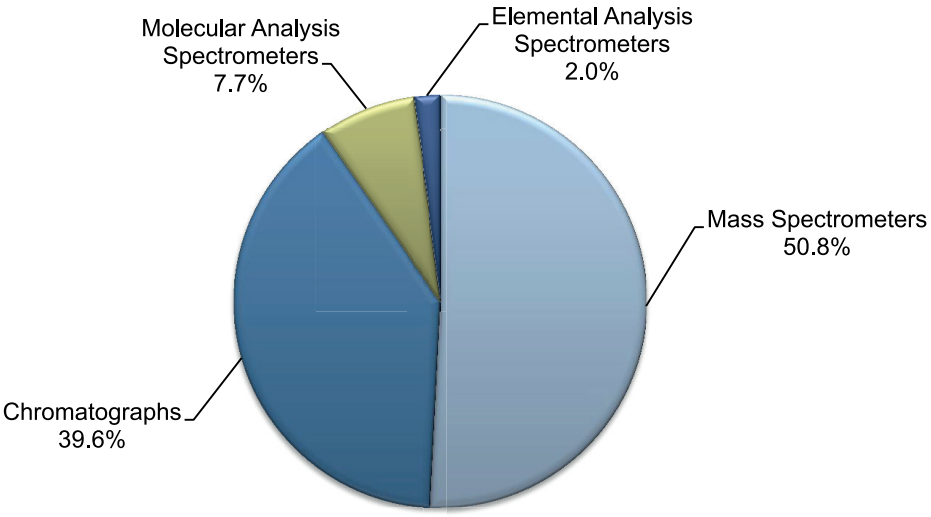
Source: Frost and Sullivan (2017) - Global Biopharmaceutical Analytical Instrumentation Market, Forecast to 2022 - Analytics Required for Biosimilar Drugs to Stimulate Market Growth.

2.14. Biopharmaceutical Analytical Instrumentation Market: Processes, Challenges and Solutions



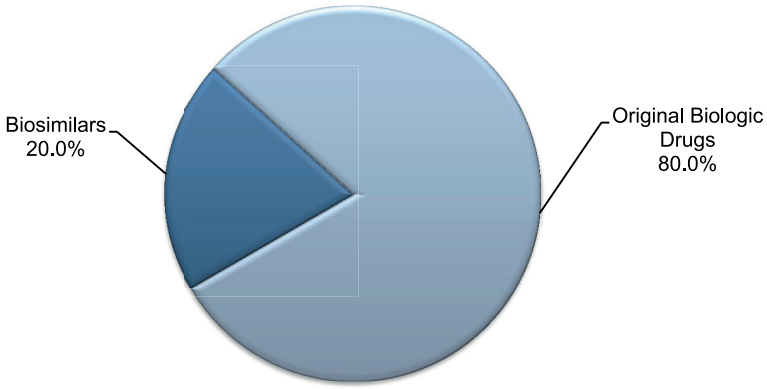
Source: Frost and Sullivan (2017) - Global Biopharmaceutical Analytical Instrumentation Market, Forecast to 2022 - Analytics Required for Biosimilar Drugs to Stimulate Market Growth.

2.15. Biopharmaceutical Analytical Instrumentation Market: Percent Revenue Breakdown by Segment, Global, 2015



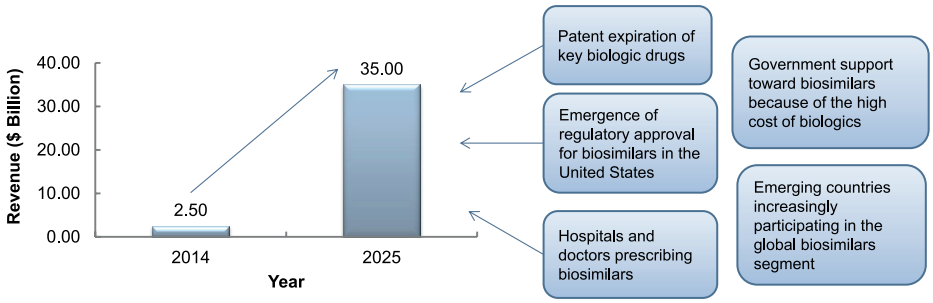
Source: Frost and Sullivan (2017) - Global Biopharmaceutical Analytical Instrumentation Market, Forecast to 2022 - Analytics Required for Biosimilar Drugs to Stimulate Market Growth.

2.16. Biopharmaceutical Analytical Instrumentation Market: Percent Revenue Breakdown, Global, 2015



Source: Frost and Sullivan (2017) - Global Biopharmaceutical Analytical Instrumentation Market, Forecast to 2022 - Analytics Required for Biosimilar Drugs to Stimulate Market Growth.

2.17. Biopharmaceutical Analytical Instrumentation Market: Biosimilars and Drivers Revenue Forecast

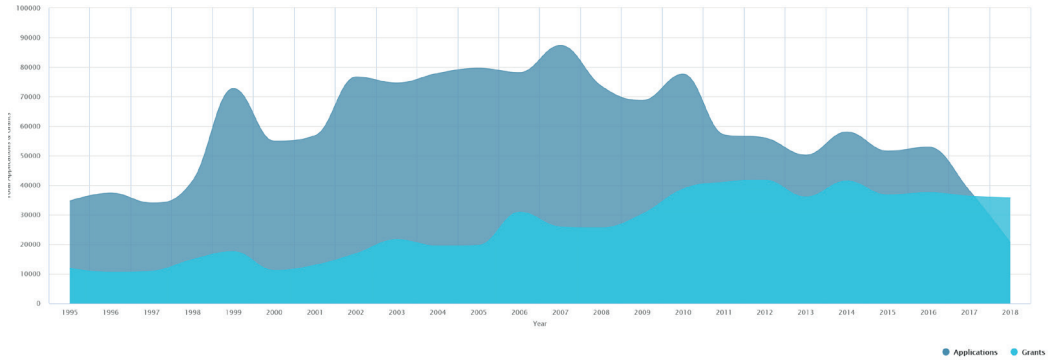


Source: Frost and Sullivan (2017) - Global Biopharmaceutical Analytical Instrumentation Market, Forecast to 2022 - Analytics Required for Biosimilar Drugs to Stimulate Market Growth.

3
Patent analysis

3.1. Evolution of patents applied for and granted

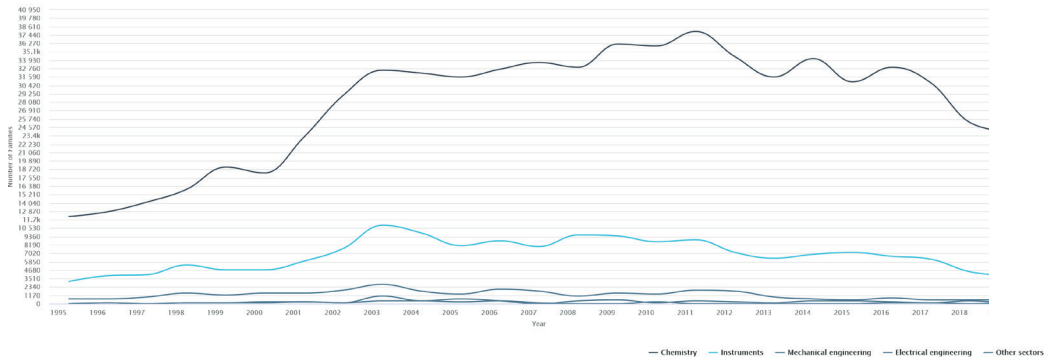
The analysis of patents applied for and granted in the area of knowledge of Biopharmaceutical production enables appreciating the **tendency for growth** over the last 25 years. While at the same time illustrating that the proportion of patents applied for and finally **granted** was **42.14%**.



Source: PatBase. November 2019 Query

3.2. Technological sector of the patents applied for

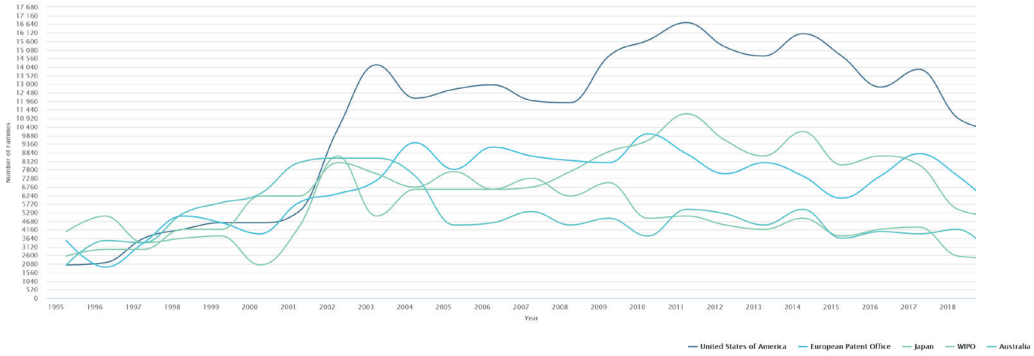
Over the last 20 years, the most active technologies in patents applied for in this area of knowledge mainly belong to the following fields: **chemistry, instruments, mechanical engineering, electrical engineering and other.**



Source: PatBase. November 2019 Query

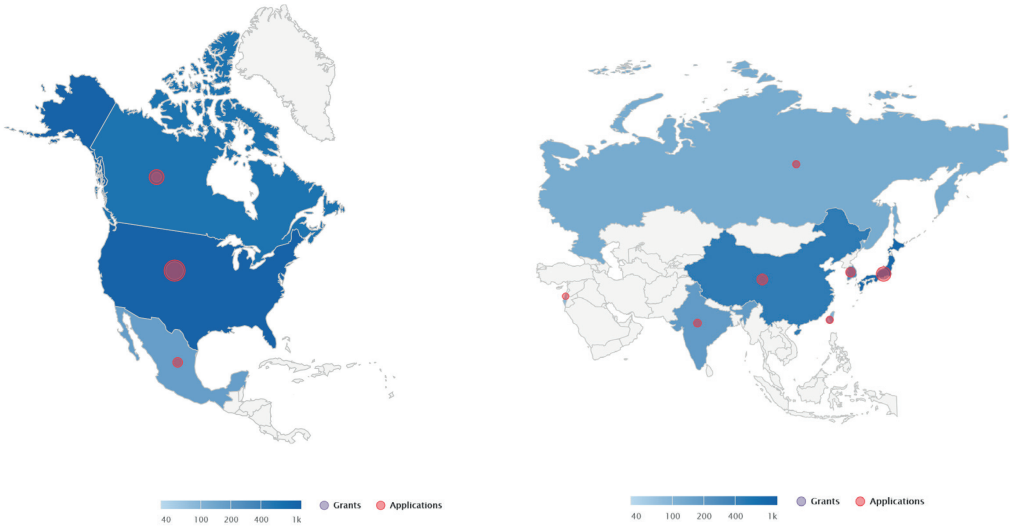
3.3. Territorial location of patents

On a **global level** for this subject, the regional offices which over the last 25 years have led the demand for patent applications are, in descending order, the United States, the European Union and Japan.



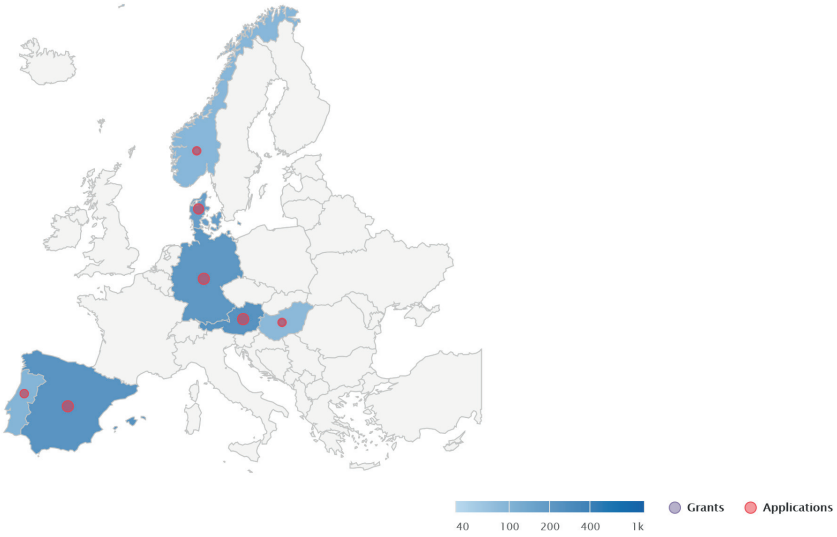
Source: PatBase. November 2019 Query

The **United States** and **Canada** are particularly active in applications in this area, as show in the graph below. In Asia, **Japan** and **China** are the most active countries, especially the former. It is also necessary to bear in mind the figures corresponding to **Australia** which is placed between these two countries.



Source: PatBase. November 2019 Query

Within the **European Union**, the countries with most patent applications are, as shown on the map below, **Austria, Spain, Germany, Denmark and Norway.**



Source: PatBase. November 2019 Query

3.4. Most active patent applicants over the last 25 years

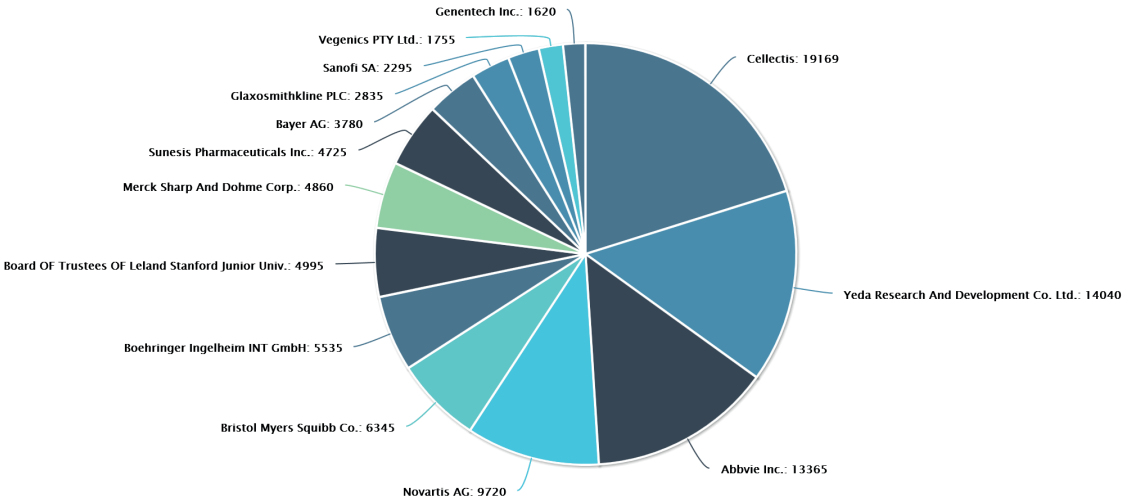
The graph below shows the five most active organisations in patent applications over the last 25 years, as well as which time periods these applications were concentrated in. Outstanding, among others, are **Novartis, Galaxosmithkline, Yeda Research and Development and Merck Sharp & Dohme.**

Source: PatBase. November 2019 Query

3.5. The most active applicants

The most active **bodies** (companies, institutions or people) filing patent applications, including the **number of applications** for each one is shown below.

The list includes **multinational biopharmaceutical companies** as well as **research institutions** such as Yeda Research and Development, an Israeli public-private institution that performs technology transfer for public centres such as the Weizmann Institute of Science.



Source: PatBase. November 2019 Query

3.6. Keywords attributed to patents in this field

The main keywords associated with patent applications in the field of study are: amine sequence, nucleic acids, proteins, cells, polypeptides, antibodies, protein preparations. This is coherent when considering that the query and patent analysis focussed on medicinal products produced by biotechnological methods, including advanced therapies (refer to the methodological appendix).

Source: PatBase. November 2019 Query

3.7. METHODOLOGICAL APPENDIX

The information provided in the "Patent analysis" section refers to the study performed on a sample of **1.540.583 patent applications** in the area of Biopharmaceutical production.

203.153	**127.291**	**1.540.583**	**1.980.229**
Patent family	Family of patents granted	Applications	Publications
Total number of families in this set of results	Total number of families with publications granted with this set of results	Applications with this result	Publications within this result

Source: PatBase. November 2019 Query

The field "Biopharmaceutical production" and its analysis was limited by considering the inclusion of medicinal products produced by biotechnological techniques; the query for these therapeutic medicinal products included

- **Proteins** (including antibodies)**, nucleic acids** (DNA, RNA or antisense oligonucleotides)
- Medicinal products such as **vaccines, blood components, allergens, somatic cells, gene therapies, tissues, recombinant therapeutic proteins and live cells** used in cell therapy.

Patent databases are organised using different international classification systems, the most common being the International Patent Classification (IPC) and the Cooperative Patent Classification (CPC) for more specific fields.

- A61K39/00: Medicinal preparations containing antigens or antibodies (materials for immunoassay G01N33/53)
- A61K38/00: Medicinal preparations containing peptides (peptides containing beta-lactam rings A61K31/00; cyclic dipeptides not having in their molecule any other peptide link than those which form their ring, e.g. piperazine-2,5-diones, A61K31/00; ergot alkaloids of the cyclic peptide type A61K31/48; containing macromolecular compounds having statistically distributed amino acid units A61K31/74; medicinal preparations containing antigens or antibodies A61K39/00; medicinal preparations characterised by the non-active ingredients, e.g. peptides as drug carriers, A61K47/00)
- C07K2317/00: Immunoglobulins specific features
- C07K16/00: Immunoglobulins [IGs], e.g. monoclonal or polyclonal antibodies (antibodies with enzymatic activity, e.g. abzymes C12N9/0002)
- C07K14/00: Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof
- C12N15/00: Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; Use of hosts therefor (mutants or genetically engineered microorganisms, per se C12N1/00, C12N5/00, C12N7/00; new plants per se A01H; plant reproduction by tissue culture techniques A01H4/00; new animals per se A01K67/00; use of medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases, gene therapy A61K48/00)
- C12N2310/00: Structure or type of the nucleic acid
- C12N7/00: Viruses; Bacteriophages; Compositions thereof; Preparation or purification thereof
- A61K45/00: Medicinal preparations containing active ingredients not provided for in groups A61K31/00 - A61K41/00
- A61K48/00: Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy

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