

Chapter: Professions

SECTIONS

01 Ethnobotony

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02 Plant Science

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04 Chemical Engineer

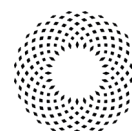
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Creating a science-based, high-tech skincare product requires a team comprised of many different professionals. This chapter examines some of the critical players who contribute to developing, manufacturing, and testing skincare products. These professionals include:

- Ethnobotanists
- Plant scientists
- Cosmetic chemists
- Chemical/Manufacturing Engineers
- Statisticians
- Regulatory Affairs Experts

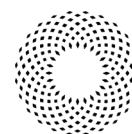
01 ETHNOBOTANY

Consumers that care about the products that go into, and on, their bodies are always searching for more natural, holistic product alternatives, as opposed to the more ubiquitous synthetic, highly processed options found everywhere in today's market. As a result, the field of ethnobotany is gaining greater relevance in product development. Ethnobotany is the study of the interrelation between a geographical region's people and cultures ("ethno") and their indigenous plants ("botany"), so as to understand the relationship between the people and their botanical world. Throughout history, and out of necessity, people have learned how to use plants and plant-based materials for food and medicine.

Because of the availability of anecdotal information relating to the traditional uses of indigenous plants, Codex Beauty has made it a part of its core mission to work with ethnobotanists, plant scientists, chemists and raw material suppliers from around the world in order to identify, and become familiar with, these novel botanical ingredients for their potential use in Codex skincare products.

Most botanical medicines are formulated by locals using plants from their indigenous surroundings. People living in disparate climates and geographies have needs that are specific to their environment. For example, tribal people living in areas with steady exposure to heat and sun will develop herbal treatments/medicines that are specific for treating conditions associated with living under such conditions. Those living in the Arctic, on the other hand, will have different region-specific conditions that are addressed by their indigenous medicines. Hence, when searching for new, novel and unique botanical skincare active ingredients, we at Codex first identify those geographical areas around the world where plants are used to treat climate-related issues and perform a thorough chemical analysis of the constituents that comprise these plants. Once the plants and their constituents are fully vetted from an analytical perspective, Codex then incorporates these actives into finished formulations that are then methodically tested for both safety and efficacy.

Moreover, Codex also believes in the importance of working closely with local suppliers of its botanical ingredients. This enables the process for extracting the plant's actives to be optimized, thereby maximizing their potency and efficacy, and also supports the local trade. This working relationship is critical to ensuring that the plant's active ingredients are sustainably/ethically sourced, clean, and manufactured using the highest quality standards.



02 PLANT SCIENCE

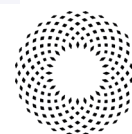
We add plant extracts to cosmetic products for various reasons—to serve as active ingredients, to provide scent or to add texture/color— all of which require the expert knowledge of plant scientists.

Plants contain many constituents such as active ingredients or phytochemicals that have a marked and definable activity on the body or skin. The branch of pharmacology devoted to the study of these constituents and their actions on the body is referred to as pharmacognosy.

There are 16 main groups of constituents found in plants which include: Alkaloids, Anthocyanins, Anthraquinones, Cardiac Glycosides, Coumarins, Cyanogenic Glycosides, Flavonoids, Glucosilates, Phenols, Saponins, and Tannins. A plant scientist working in the field of cosmetics will need to understand what effect a cosmetic product is targeting and then consider the range of constituents that can facilitate that effect. Once the appropriate constituents are identified, the scientist must then determine the best process for extracting them from the plant, which will depend on whether they are water or oil soluble, if they require a unique solvent, and whether they are heat sensitive, since any one of these variables can have an impact on the quantity and/or quality of the constituents being extracted. Lastly, he or she must also take into consideration whether any undesirable effects and/or problematic interactions may be realized during the extraction process.

Constituents can be isolated and extracted individually; a range of constituents can be extracted simultaneously; or the entire plant and all of its constituents can be used. The beauty of working with plants is that different constituents can work together in beneficial or even synergistic ways. A plant scientist will understand these complex relationships and be able to choose the most appropriate extracts.

A plant scientist can also analyze an extract and tell what constituents are present and in what concentrations by running various assays which can be helpful from a quality point of view. Plant extracts can be easily contaminated either because of comingling with other species of plants, or if the wrong part of a plant was used during the extraction process. Having an expert involved in all stages of growing, harvesting, and processing is vital.



03 COSMETIC CHEMISTRY

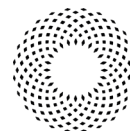
Today, consumers have a variety of different types of cosmetic products to choose from, such as those intended for use on one's skin, hair or nails for the purpose of cleansing, hydrating, protecting and enhancing the appearance of these areas of the body. While most cosmetics contain conventional ingredients such as water, emulsifiers, preservatives and fragrance, the key ones are those that facilitate the desired benefit known as "active ingredients." While these ingredients can be either naturally derived or synthetic, their potential impact on a person's health is dependent on their chemical makeup. Because there are literally thousands of cosmetic products available on the market, each of which contain numerous ingredients, the overall number of ingredients and combinations that a person applies onto their body is astounding. In the United States, there are over 10,000 unique chemical ingredients approved for use in personal care products. A single cosmetic product will typically contain anywhere from 15 to 50 ingredients. Studies have shown that a woman, on average, applies from 9 to 15 products on her body each day, not counting perfume. That means that a woman's body is exposed to over 300 chemicals each and every day as part of her normal personal care routine. Statisticians estimate the daily number to be closer to 515, inclusive of perfumes.

Although cosmetic chemists are often thought of in the industry as being like artists or chefs, always striving to create products that are as unique and elegant as they are useful, they are also in fact scientists, having obtained at least a bachelor's degree and often times a post-graduate degree, in a chemical discipline. As a result, they possess a requisite amount of knowledge and understanding as to how the different types of ingredients in a formula interact with one another to ensure that their creations are both safe and efficacious. To that end, they work closely with toxicologists, dermatologists and ingredient suppliers, to make sure they are aware of the latest, most relevant information concerning the ingredients in their formulas. Regardless of whether the product is an anti-aging skin care lotion, a hair shampoo or a nail polish, it must first and foremost be safe and only then, efficacious as well.



04 Manufacturing (Chemical Engineer) with GMP Experience

Consumers expect that every product they use will meet quality standards so that they will be safe and effective. Current Good Manufacturing Procedures (cGMPs) include establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable test methods. This formal system of controls, when adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that the products consumers use will meet their quality standards.



Chemical engineers, using cGMP practices, design and apply methods that combine ingredients for cosmetics and personal care products. The engineer takes a formulation or recipe of ingredients developed by the Research & Development team and commercializes the production on a larger scale by blending them together using various methods such as heat, cold, and mechanical energy. One such technique is creating an emulsion— a process that forces oil and water together by using an agent to stabilize molecules producing lotions and creams.

A highly technical profession, manufacturing engineers are responsible for fine-tuning production efficiency and reducing expenses as much as they can. On a daily basis, Manufacturing Engineers communicate manufacturing capabilities, production schedules, or other information to facilitate production processes. They apply continuous improvement methods such as lean manufacturing to enhance manufacturing quality, reliability, or cost-effectiveness.

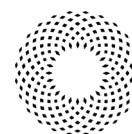
Sustainable manufacturing integrates operational improvements that reduce the environmental impacts of manufacturing processes. Integrating sustainable practices into manufacturing operations to improve environmental performance including: Energy efficiency practices, water conservation, elimination of waste and emissions, internal recycling of waste, closed loop and industrial ecology processes.



05 STATISTICIAN (HUMAN AND IN-VITRO STUDIES)

At Codex Beauty, the safety and efficacy of our products, in that order, are our top priority. We want users to feel validated in their belief that the products they are applying on their skin are both safe to use and will yield the expected result.

The most objective, reliable way of assessing a product's safety and efficacy is via the use of data generated by robust clinical testing. This is where the role of a statistician becomes critically important. Statisticians assist in the development and application of statistical methods and models in their evaluation of products. Working in cooperation with dermatologists and clinicians, they gather, analyze, and interpret data generated by safety and efficacy studies.



Most statisticians have at least a master's degree in either statistics or mathematics. Once they have acquired this foundational academic background, expertise in a specialized industry such as skincare is then gained through hands-on experience.

To be successful in their chosen profession, statisticians must possess a combination of analytical, technical and communication skills. Statisticians must first be experts in statistical analysis with an ability for detecting patterns/trends and anomalies in data. Next, they must be able to utilize various technologies such as computer systems, software programs, algorithms and other types of technologies, so they can effectively collect and interpret the data that informs their actions and conclusions. Lastly, even though statisticians are experts in mathematics and statistics, they must also have strong communication skills to be able to clearly and effectively communicate their findings and conclusions.



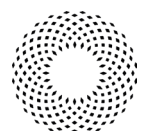
So, the next time you apply a Codex product on your skin, rest assured that objective, reliable safety and efficacy data has been collected, analyzed and interpreted by a highly educated, skilled professional who takes number crunching VERY seriously.

06 REGULATORY AFFAIRS

When it comes to beauty and personal care products, a company's regulatory affairs group is tasked with overseeing how their products are developed, tested, manufactured, marketed and distributed to ensure they are in compliance with all of the regulatory standards in whatever geographical area(s) they are being sold.

Regulatory professionals come from a variety of backgrounds. They typically have cross-functional training in areas such as science, pharmacy, engineering, marketing and business. According to a 2016 Regulatory Affairs Professionals Society report, over 88% of current regulatory professionals began working in a different industry prior to transitioning into regulatory affairs. Most initially worked in a related industry such as research and development, manufacturing, clinical research, labs sciences, pharmacology and engineering. In addition to an undergraduate degree, because most employers require these professionals to have advanced knowledge and hands-on experience, qualifications that can be gained in a graduate program, many possess an advanced degree as well. Regulatory affairs specialists have a lot on their plate. In addition to being familiar with, and analyzing, both new and existing regulations relating to their company's products or processes, they are also responsible for reviewing marketing, legal and technical documentation including case files and clinical research reports to assess compliance with global regulatory agency policies, regulations and standards.

Since cosmetic products are sold globally, it is imperative that regulatory affairs specialists have a global perspective and knowledge base, as each country has its own regulatory rules and regulations. As a result, cosmetic chemists/formulators work together with regulatory specialists to make sure that they develop innovative products that not only provide a "wow-factor" in the marketplace, but also stay within the confines of the laws in each country.



Aside from ingredients approval and prohibition, regulatory specialists must keep formulators in the loop regarding whether a product is a cosmetic or a drug. For example, in some countries like the US and Japan, products such as sunscreens and antiperspirants are considered quasi-drugs. In the EU, anti-aging products are considered borderline products meaning they straddle the line between cosmetics and drugs. It is because of the lack of harmonization that several different iterations of the same product must be formulated for global sale.

Today, regulatory bodies around the globe are going through a revolution, putting certain restrictions on, or outright banning, chemical ingredients like formaldehyde, dibutyl phthalate, parabens and many others once considered safe. Regulatory experts need to work closely with formulators to relay new regulatory information so that they understand the parameters under which they may develop a new formula.

There are 193 countries in the world, each of them with its own set of ever-changing standards/rules/regulations that must be respected. Not only do federal/country specific laws need to be followed, but state laws as well. For example, California has one of the strictest laws in the nation when it comes to the safety of products sold within its borders. Hence, whether selling products in the US or internationally, it's important for a company to define solid testing protocols and develop claims that hold up under scrutiny when dealing with non-harmonized regulatory environments.

Each company that sells cosmetics must decide which specific standards apply to its products, and what it must do to ensure full compliance with global existing and emerging legislation. This goal is achieved when the regulatory affairs professional works cross-functionally with the various product-related groups within an organization such as marketing, R&D and manufacturing. It is through these collaborations that creative, yet comprehensive regulatory compliance programs, which the regulatory affairs group is charged with overseeing and implementing throughout a product's lifecycle, are realized. As the old saying goes, "it takes a village" and consequently regulatory affairs professionals definitely have a seat on the village counsel.

