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Review Article

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Characterization and Comparison of quality management systems for cosmetic products in the world

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Abstract

The quality management systems are tools that can be implemented in different types of industry with the purpose of achieving improved quality standards on the products or services they develop, mainly looking to satisfy the customer and position themselves in the market with an advantage over the products offered.

Within the pharmaceutical industry there are numerous regulations and laws that regulate and supervise the production of these products worldwide, ensuring that the industries dedicated to this area have certain regulations and meet minimum quality objectives, because they are products that have a high impact on human life and their improper use can mean major problems for it. This is why, over the years, organizations have been formed.

It corresponds to a bibliographic review of international regulations on the manufacture of cosmetic products. Multiple sources are reviewed, from the original standards that contain the minimum requirements for a company that manufactures this type of product, to reviews by auditing and consulting organizations, as well as research on the same subject.

It is important to note that basically all regulations, rules and standards specify the same requirements to meet the needs of the customer, and at the same time, meet the safety and quality of a product that will circulate both in domestic and international markets. In this sense, it is clear that the most widely used standard worldwide is ISO 22716:2007, which is widely disseminated across all continents, and is used as the basis for many of the national regulations implemented in countries. The changes made by local regulations are minimal to the content of the standard, adding some clauses to it, but leaving its basic structure intact.

Keywords: Cosmetics, Good Manufacture Practices, Pharmaceuticals, Quality Management Systems

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1. Introduction

The quality management systems are tools that can be implemented in different types of industry with the purpose of achieving improved quality standards on the products or services they develop, mainly looking to satisfy the customer and position themselves in the market with an advantage over the products offered. (1)

Within the pharmaceutical industry there are numerous regulations and laws that regulate and supervise the production of these products worldwide, ensuring that the industries dedicated to this area have certain regulations and meet minimum quality objectives, because they are products that have a high impact on human life and their improper use can mean major problems for it. This is why, over the years, organizations have been formed to analyze and regulate the production, sale, export and import of these types of products. (2,3)

When speaking specifically of cosmetic products, these are regulated by the same organizations already mentioned, but they have different regulations created especially for the cosmetic industry, these regulations can vary according to the country where they are made and or sold; so it is fundamental that if you want to incur in this pharmacological area you must know the regulations stipulated in this respect. (4)

This document develops a research on the main quality management systems around the world and those present

in Costa Rica, detailing what is dictated by these regulations and the differences between them.

2. Study material

It corresponds to a bibliographic review of international regulations on the manufacture of cosmetic products. Multiple sources are reviewed, from the original standards that contain the minimum requirements for a company that manufactures this type of product, to reviews by auditing and consulting organizations, as well as research on the same subject.

3. Results and Discussion

Table I. Regulations in Costa Rica and other regions of the world

Region	Current regulations
Costa Rica	The international standard ISO 22716:2007 stands out, which specifies the good manufacturing practices for cosmetic products. (5–7) The Central American Technical Regulation RTCA which stipulates different resolutions related to cosmetic products. (8) • RTCA 71.01.35:06 which details the regulations corresponding to the registration and sanitary inscription of cosmetic products. • RTCA 71.03.49:08 on good manufacturing practices for laboratories manufacturing cosmetic products. • RTCA 71.03.45:07 about quality verification for cosmetic products. • RTCA 71.03.36:07 for the Labeling of Cosmetic Products.
United States	The Guide for Industry: Good Manufacturing Practices in Cosmetics which provides guidance for industry and stakeholders on GMP in cosmetics and aims to assist the industry in identifying standards and issues that may affect the quality of cosmetic products. (9)
Europe	The guidelines and conditions from the European Parliament and Council Regulation: • Article 10 which details the guidelines and conditions that cosmetic products must meet in order to be allowed to be sold in these countries. (10) • Regulation No.1223/2009 which is a regulation created for the market of cosmetic products sold and distributed within the countries that make up the European Union. (11,12) • Decision 96/335/EC which establishes a common nomenclature for the ingredients used in the manufacture of cosmetic products with the aim of achieving better control over the products that are analyzed. (13) The guidelines based on the legal protocols from The European Trade Association for Cosmetic and Personal Care Industry (COLIPA): • Efficacy Guide for the evaluation of cosmetic products. (14) • Stability testing of cosmetic products Guide to ensure that new or modified products meet physical, chemical and microbiological quality requirements, as well as functionality and aesthetics. (15)
Germany	The general Guidance for Manufacturers and Distributors of Cosmetic Products which is divided into articles concerning safety requirements, responsibilities, obligations, good manufacturing practices, product information documentation, notifications, restrictions, traceability, animal testing, labelling, and access to information for the public. (16)
England	The guidelines established for auditing organizations in the field of cosmetic products set by The Cosmetic Toiletry & Perfumery Association Limited (CTPA). (17)
Ireland	The guide called the HPRA Guide to Good Manufacturing Practice of Cosmetic Products, which provides guidance to companies on good practice in cosmetics, in addition to the requirements of ISO 22716:2007. (18)
Spain	The Quality Systems of the Cosmetic Industry for the Valencian Community, prepared by the Regional Ministry of Health which contains measures that have been implemented by the industries regarding the production of cosmetics and the evolution of this type of products. (19)
Japan	The guideline name Cosmetic Standard by the Japan Ministry of Health, Labor and Welfare that specifies the list of prohibited ingredients, as well as the maximum permitted amounts of certain compounds, where it also specifies in which types of products these ingredients may or may not be applied. (20)
South Korea	The regulation is based on ISO 22716 and considers product risk, hazardous substances, label information, testing methods and GMP qualification at manufacturing sites. (21) The Korean Cosmetics Act which compiles the regulations for the manufacture, import and sale of cosmetic products. (22)
Taiwan	The TFDA uses the Cosmetic GMP Standard, based on ISO 22716. In the future the TFDA plans to build an archive of product information and records, using the CNS 22716 standard, and thus build a good manufacturing practice program specific to Taiwan. (23)

Jordan	The Good Manufacturing Practices by the Jordan Institute of Standards and Metrology which was adopted by the ISO cosmetics committee.
Canada	The FDA Consolidation in which the conditions under which the sale of cosmetics is prohibited within the country are described. (24) The Cosmetic Products Regulation, issued and approved by the Canadian Ministry of Justice, through which the review and acceptance process that must be carried out to the products that enter the country is detailed, and also the established protocol for taking samples of the products and detailed regulations regarding the labeling and sale of products in the cosmetic area. (25)
Nigeria	The Good Manufacturing Practices (GMP) were written in 2018 by the NAFDAC and are focused on cosmetic products. • The norm DER-GDL-004-00 take in consideration general considerations, personnel, organization, qualifications and responsibilities, training, premises, storage areas, equipment, hygiene and sanitation, production, quality control, documentation, internal audit, external contracts and analysis, complaints and claims and terms and definitions. (26)
Venezuela	The Manual for Good Manufacturing Practices for Cosmetic Products by CAVEINCA, seeking to guarantee the quality of cosmetics and drugs in each of their manufacturing stages. (27)
Colombia	The Good Manufacturing Practices, with the certifying body of ISO 22716:2007. (28) Also, as a member of the Andean Community of Nations (CAN), is regulated by the legislation on cosmetic products, created Decision 516, 2002, in which they adopted the Harmonized Technical Standard for Good Manufacturing Practices for Cosmetics. (29)

Definition of cosmetics

The cosmetics and personal care products can be different types of formulations, which are applied in a corporal way and have diverse uses, advantages and presentations. Due to their massive use by the world population, it is necessary to define regulations in their formulations, treatment, production and logistics. (30)

First, it is appropriate to define cosmetic products themselves, which, according to Article 2 of Regulation (EC) No 1223/2009 of the European Parliament, are defined as: 'any substance or mixture intended to be placed in contact with the superficial parts of the human body (epidermis, hair system, capillary system, nails, lips and external genitalia) or with the teeth and oral mucous membranes, solely or mainly for the purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours'. On the other hand, the U.S. Food and Drug Administration (FDA), in section 201 of the Federal Food, Drug, and Cosmetic Act, defines them as: "articles intended to be rubbed, poured, sprayed, introduced, or otherwise applied to the human body for the purpose of cleaning, beautifying, promoting attraction, or altering appearance. As can be seen, the definitions corresponding to both entities are complementary, where one delves into the areas where cosmetics are applicable, while the other specifies the forms of application. (30–32)

Some examples of cosmetic products are skin moisturizers, perfumes, lipsticks, nail polish, eye and facial make-up preparations, soaps, shampoos, conditioners, hair dyes and deodorants, or, in short, any substance used as a component of a cosmetic product. (30)

History of Cosmetics

According to the World Health Organization (WHO): "Health is a complete state of physical, mental and social well-being and not merely the absence of disease or infirmity": Taking this into consideration, proper care of the outside of the body contributes to the complete well-being of the human being, which explains the high demand for products of this type throughout history. It is necessary to emphasize that, historically, different civilizations have had different notions of what is called "beauty", which is the main purpose of cosmetic products. In this aspect, each of these cultures has used (and uses) mineral products, animal products, plants and chemical synthesis. (33)

The first records of the use of cosmetics date back to 10,000 B.C., in the Ancient Egyptian Civilization, where its inhabitants used aromatic oils and ointments to soften and clean their skin, as well as to mask their body odor. In addition, they used colored dyes on their skin, hair and body, along with henna tattoos. However, in Egypt these components were not only used for beautification, but also for protection from the sun, as well as for performing religious rituals and embalming the dead. Later, around 3,000 B.C., ointments began to be used in China, along with perfumes, incense and fragrances, such as jasmine aromas. The use of these products spread across the globe, reaching ancient civilizations such as India, Persia, Mesopotamia, and Assyria, as well as various African cultures. Also, it is noteworthy that some Native American tribes painted their faces using natural products, for battles or ceremonial events. (34)

Later in recent history, there are records that the first cosmetic deodorant was invented in Philadelphia in 1888, to start a growing makeup industry in the 20th century in the United States. The popularity of theaters, operas, ballet, and the birth of the movie industry in Hollywood led to a rapid growth of the market, where, for example, in 1907 L'Oréal was founded and in 1914 Maybelline, where simple makeup products were sold.

Over time, lipstick, nail polish and other types and devices were introduced, until the industry reached the commercial boom with which it is known today. In addition, considering the growth of the media and globalization, this market is likely to continue growing, adapting to different and new trends, and selling billions annually. (34,35)

Economic aspect in Costa Rica

The cosmetics industry has experienced growth as a result of the increased participation of this type of product in international markets. In this sense, in 2012, exports of these products in Costa Rica totaled $20 million, with destinations to North America (43%), Central America (42%), and Europe (10%). The magnitude of these exports can also be seen by analyzing the behavior of which between 2008 and 2012, where its value increased from 11 million to 20 million dollars, with a growth of 80%. Within this, orange oil stands out, which corresponds to a third of exports, with 36.4%, followed by soaps with 21.2%. On the other hand, the product with the highest growth in the mentioned period is the repellent for body use, with an average annual growth of 72%, followed by perfumes and toilet waters, with 71%. (30)

Quality control of cosmetic products

The quality of the cosmetics is defined by the characteristics that the producer chooses to have, based on the customer's requirements. On the other hand, the quality control of a product seeks to verify that all those quality characteristics are in accordance with standard definitions and are maintained throughout the life of the product. Quality control of cosmetics is important to ensure the efficacy and safety of products and raw materials. (36)

The use of international standards, regulations and specifications allows the standardization of minimum requirements that this type of products must contain, achieving the standardization of the characteristics and minimum products that a cosmetic can present.

It is fundamental that the pharmaceutical industries or persons related to them have knowledge about the laws related to the area of drugs, pharmacology, and the cosmetic area in general, as proposed by Al-Worafi and Clark (2,37), it is fundamental that each person involved in the process of manufacturing or selling cosmetic products knows their responsibilities and duties according to the regulations or laws that correspond to them; as well as the organization in charge is aware of the legal standards to which they must respond in terms of quality when manufacturing cosmetics.

On the microbiological side more specifically, cosmetic products are widely considered to be suitable for the growth of microorganisms, which causes organoleptic alterations and changes in viscosity and color and can also be potentially dangerous for humans. For this reason, there is European and American legislation that indicates that companies are responsible for the safe use of this type of product, implying that a marketed product has to be free of microbiological contamination. According to this, the use of a PIF (Product Information File) is necessary for each product, which contains a lot of information, including physical-chemical stability, traces, impurities, package interactions and the right amount of microbes in the raw materials and finished product. (38)

The aspect of respiratory exposure to cosmetic products or ingredients is also considered, since there is the presence of aerosol or powdered cosmetic products that, when inhaled, can present problems in the respiratory system and, depending on the level of toxicity that it possesses, can represent severe problems in human health. For this reason, the main regulations should include a review of the ingredients that make up the products that will be placed on the market to ensure that their toxicity levels are not high enough to compromise the health or life of people, and to establish the appropriate safety measures when applying or using the cosmetic. (39)

Continuing with the theme of toxicity, it is necessary that the industries that produce cosmetics have an adequate and transparent determination of the elements that are used in their products, since the constant use of certain ingredients or daily exposure to them can generate problems in the health of customers. As there are different regulations and studies that may vary regarding the maximum levels of use of some of the ingredients, it is necessary for industries to investigate this issue and to follow the regulations of the markets to which they are going to sell, since a small variation in the compound used can generate great repercussions on health. (40) An example of this can be found in the reference tables created by the Cosmetic Ingredient Review. (41) where ingredients frequently used in the cosmetics industry and their corresponding potential health hazards are established, as well as the concentrations in which they should be used.

Related to this, it is important for the organizations of the cosmetic industry to implement quality management systems for their products since having this allows a continuous review that commits the company to improve its performance; even for some regulations, as we will see later, it is a requirement that a company has this system properly defined to allow the sale of their products. For this purpose, it is important that the company achieves an adequate design of the quality system and its correct implementation, making use of a quality manual that allows the organization to guide itself and execute its work in a better way. (17) In this way, as Melo and Moncada (42) explains, it is necessary that these systems be implemented, since the cosmetic industries have the responsibility to evaluate and verify that the products they make comply with quality tests and are safe to be used by the clients, thus preparing a review plan for microbiological, physicochemical, and organoleptic tests that allow them to know the quality of the developed product.

Regulations applicable to Costa Rica

Regarding the regulations related to cosmetic products applicable in Costa Rica, the international standard ISO 22716:2007 stands out, which specifies the good manufacturing practices for cosmetic products.

This certification ensures compliance and verification of good practices throughout the entire production process, considering from the entry of raw materials, processing and production, relevant quality controls, required hygiene and ending with the packaging, storage and dispatch of products. These specific regulations must and requirements in the area of personnel, where it is specified that the organization must have an organization chart, the responsibilities of the high management as well as of the personnel must be properly defined, training on the Practices of Good Manufacture and other trainings must be developed that provide the necessary knowledge so that the workers can develop their tasks satisfactorily fulfilling the regulation; as it was mentioned previously this regulation counts on a section directed towards the hygiene that must maintain the personnel of the company. On the other hand, the area of the facilities is also considered, where a detailed description of the design and maintenance of all work areas is found, as well as their respective cleaning and disinfection. (5) There is then a chapter on the equipment used in the organization, considering its proper design, cleaning and maintenance. (6)

As explained in Good Manufacturing Practices for Cosmetic Products ISO 22716 (7) the implementation of this regulation on an organization means numerous advantages that, in the case of the Costa Rican market, implies great advances in the development of this industry. Some of these advantages are that, by having a certification in the regulation, it facilitates the access of the organization to incorporate itself in international markets, as well as it allows guaranteeing the clients a high degree of quality on the products offered, allowing an improvement on the image of the company and generating more confidence on the use of its products.

A case of the application of ISO 22716 in a cosmetic products company is carried out by the Polytechnic University of Catalonia. In this work, it is emphasized that with the norm, the contamination of the products can be reduced, but it is impossible to reach a perfect protection, because the possibility of contamination always exists. The norm specifies rules of how everything must be to be able to pass an audit, but it does not say which are the actions that must be carried out to be able to obtain it, so that everything is adjustable to companies of different types. (43)

Continuing with applicable regulations in Costa Rica, there is the Central American Technical Regulation RTCA which stipulates different resolutions related to cosmetic products; on the one hand, there is RTCA 71.01.35:06 which details the regulations corresponding to the registration and sanitary inscription of cosmetic products, where the requirements that a company must fulfill to obtain the sanitary registration for the elaboration and commercialization of cosmetic products are established. There is the RTCA 71.03.49:08 on good manufacturing practices for laboratories manufacturing cosmetic products, this regulation specifies the good practices that must be implemented and maintained during the manufacture of cosmetic products. Then, there is the RTCA 71.03.45:07 about quality verification for cosmetic products. This regulation establishes the evaluations and tests that must be performed to ensure the quality of the products and that they comply with the established specifications. Finally, there is the RTCA 71.03.36:07 for the Labeling of Cosmetic Products, this regulation consists of specifying the information that must be detailed on the label of cosmetic products. (8) This regulation is supported by the Ministry of Health of Costa Rica, which is the body in charge of ensuring that companies comply with the specifications of the regulation.

Regulations in other regions

In almost all countries that manufacture cosmetic products, there is specific information and regulation for this type of practice, in order to ensure conformity with specifications and consumer safety, by meeting minimum requirements. In this section, the most relevant aspects of the regulations that apply in various regions around the world are discussed.

In general, there is a global system for the approach of names for cosmetic products, which contributes to the transparency provided to consumers, regardless of the country of origin of the product. This system is called the "International Cosmetic Ingredient Dictionary and Handbook", and it provides technical and descriptive information on the materials identified as potential for use as cosmetic products. Some of the countries using this type of regulation are Argentina, Australia, Canada, China, Colombia, Israel, Korea, Mexico, Norway, Saudi Arabia, South Africa, Brazil and Costa Rica. (44)

a) United States

This country is governed primarily by the provisions of the U.S. Department of Health and Human Services, specifically its Food and Drug Administration (FDA). This body published in 2013 the Guide for Industry: Good Manufacturing Practices in Cosmetics, which provides guidance for industry and stakeholders on GMP in cosmetics and aims to assist the industry in identifying standards and issues that may affect the quality of cosmetic products. However, it should be noted that this regulation is not legally binding, but only represents the thinking of the FDA in terms of recommendations. In this sense, it is recommended to keep documentation and records of the activities performed, as well as specifications for the buildings and equipment used in the processes. Likewise, guidelines are mentioned to be complied with in terms of personnel requirements, for example, that they have the appropriate skills, and also in terms of the raw materials to be used and the way in which they should be handled. Finally, suggestions are made regarding production, laboratory control, internal audit and complaints. It is important to note that the guide mentions a series of components that are prohibited for making cosmetics, including chloroform, mercury compounds, hexachlorophene, chloro-fluorocarbons, and methylene chloride, among others. (9)

b) Europe

In the case of Europe, there are different rules and regulations depending on each country, but in a general way, the European Parliament is responsible for

regulating and legislating the agreements issued regarding the export, import and manufacture of cosmetic products, these guidelines must be applied by all countries belonging to the European Union. The European Parliament and Council Regulation, which describes the issues related to the cosmetic industry in Article 10, details the guidelines and conditions that cosmetic products must meet in order to be allowed to be sold in these countries. (10)

Also issued by the European Parliament and the Council of the European Union (11) is regulation No. 1223/2009 which is a regulation created for the market of cosmetic products sold and distributed within the countries that make up the European Union. This regulation seeks to ensure the safety for human health of those who use these products, as stipulated in Chapter II of this standard, which specifies the requirements for production, handling, labeling and storage of products. It also provides an exhaustive description of the responsibilities of the persons in charge of the production and distribution of the products, and a list of the products that are prohibited or restricted to produce cosmetics.

Similarly, issued by the European Parliament and the Council of the European Union (12) on cosmetic products and related to Regulation 1223/2009 are the guidelines on Annex I, which describe the safety aspects of cosmetic products; this Annex is composed of two main parts, the first consisting of the respective product safety information which is used for the identification of risks and potential health hazards posed by the product. In this information, the composition of the product, its microbiological quality and its physicochemical specifications are detailed, as well as a description of side effects, toxicity and dosage. Subsequently, corresponding to the second part of the annex, this consists of the safety evaluation of the product where the information obtained by a safety evaluator is included. This evaluator must review the compliance and veracity of the information provided with respect to the cosmetic product, thus providing the conclusions and final approval required for the product.

Within the European Union in 2006 Decision 96/335/EC was issued which establishes a common nomenclature for the ingredients used in the manufacture of cosmetic products with the aim of achieving better control over the products that are analyzed. This decision lists the products that are allowed to be used in the manufacture of cosmetics within the European Union, their established nomenclature and the function that each ingredient fulfils, facilitating and improving the review of products and the quantities in which they are used. (13)

There is also "COLIPA" which corresponds to "The European Trade Association for Cosmetic and Personal Care Industry" which is responsible for representing the cosmetic industry in Europe. It produces guidelines based on the legal protocols issued by different authorities, so that individuals involved in this industry can follow and comply with the necessary requirements. It has the Efficacy Guide for the evaluation of cosmetic products, which details the assessment methodologies to be implemented, as well as specifying the reports to be generated and the information to be collected for subsequent submission for product approval. (14) This guide also includes a marketing ban for cosmetic products that have been tested on animals. Its value lies in the need to have a package of information regarding these types of products, focusing on consumer health, for example, on skin compatibility. (45) In addition, another document, Cosmetics Europe, details the COLIPA guidelines to ensure that new or modified products meet physical, chemical and microbiological quality requirements, as well as functionality and aesthetics when stored in appropriate conditions; this is called a stability testing programme, which ensures the stability of the products on the market. This takes into account both product characteristics, packaging, storage and environmental conditions. (15)

On the other hand, in Germany there is a specific guide, called General Guidance for Manufacturers and Distributors of Cosmetic Products in Germany, which is divided into articles concerning safety requirements, responsibilities, obligations, good manufacturing practices, product information documentation, notifications, restrictions, traceability, animal testing, labelling, and access to information for the public. It should be noted that this guide is based on the international European regulation, mentioned above, but has specific compliance guidelines for Germany. (16)

In England, The Cosmetic Toiletry & Perfumery Association Limited (CTPA) has a set of guidelines established for auditing organizations in the field of cosmetic products. It states that audits of microbiological control management should be carried out regularly to ensure that quality systems are working properly, that products are being made in accordance with specifications, that procedures are being followed and that records are being kept. Audits are made of warehouse, distribution, water, microbiological facilities, laboratory controls, research and development, complaints and claims, engineering and maintenance, purchasing, outsourcing, personnel and training. (17)

In addition, in Ireland, there is a guide called the HPRA Guide to Good Manufacturing Practice of Cosmetic Products, which provides guidance to companies on good practice in cosmetics, in addition to the requirements of ISO 22716:2007. The regulation defines requirements for laboratory quality control, waste, subcontracting, treatment of off-spec products, deviations and unfinished products, which are not addressed by the ISO standard in question. (18)

Finally, a book is presented for the case of Spain on the Quality Systems of the Cosmetic Industry for the Valencian Community, prepared by the Regional Ministry of Health, which is responsible for ensuring compliance with the legislation and regulations established for products in this area. This book contains a collection of the measures that have been implemented by the industries regarding the production of cosmetics and the evolution of this type of industry in the country. In this way, although the book created is not a regulation

as such, it offers advice and clear explanations to the manufacturers of these products on how to proceed with their elaboration and adequate handling. (19)

c) Japan

The Ministry of Health, Labor and Welfare oversees the regulation of cosmetic products in Japan. It issued the Cosmetic Standard, which is governed in accordance with the Pharmaceutical Affairs Law, the Cosmetic Quality Standards manual and the Japanese Cosmetic Ingredient Statute. This Cosmetics Standard specifies the list of prohibited ingredients for the manufacture of these products, as well as the maximum permitted amounts of certain compounds, where it also specifies in which types of products these ingredients may or may not be applied. (20)

d) South Korea

The Ministry of Food Safety and Drugs (MFDS) is responsible for the cosmetics and personal care sector, where they take control of product risk, hazardous substances, label information, testing methods and GMP qualification at manufacturing sites. Product launches need to take into account the list of prohibited substances for cosmetics. The Korean regulation is based on ISO 22716. (21)

There is also the Korean Cosmetics Act created in 1999 which compiles the regulations for the manufacture, import and sale of cosmetic products, this act states that the ingredients used for the production of cosmetics must be approved by the MFDS, as well as this act establishes the safety standards for these same products. (22)

e) Taiwan

The Taiwan Food and Drug Administration (TFDA) is the government body responsible for regulating cosmetics in this country. The certification uses the Cosmetic GMP Standard, based on ISO 22716, which is voluntary. Currently, 34 factories have a certificate from this body. In the future, the TFDA plans to build an archive of product information and records, using the CNS 22716 standard, and thus build a good manufacturing practice program specific to Taiwan. (23)

In the magazine "Food and Drug Analysis" a compilation of surveillance projects on cosmetic products in Taiwan is elaborated where it is achieved through the review of these projects, to determine which are the cosmetic products in which a greater level of nonconformity or noncompliance with the regulations is presented, through these investigations it is possible to determine the lack of synchrony between government entities, health and the cosmetic industry to achieve high quality products in the market that are safe for the health of the consumers. (46)

f) Jordan

The country is a member of the ISO 217 Technical Committee, and the Jordan Institute of Standards and Metrology has established a manuscript of good manufacturing practices, which was adopted by the ISO cosmetics committee. Therefore, products manufactured in Jordan, mainly for skin and hair care, can be considered as a good reference for compliance with standards. (47)

g) Canada

In Canada, cosmetic products, as well as over-the-counter medicines and natural products are regulated by the FDA (Food and Drugs Act) and these must be duly registered and accepted by the Canadian health system. When talking specifically about cosmetic products, there is the FDA Consolidation in which the conditions under which the sale of cosmetics is prohibited within the country are described. This specifies that the products for sale must have a sanitary registration and license, which ensures that the components of the products do not pose any kind of danger to customers and must ensure that they have been manufactured in proper conditions. (24)

Likewise, there is the Cosmetic Products Regulation, issued and approved by the Canadian Ministry of Justice, through which the review and acceptance process that must be carried out to the products that enter the country is detailed. For these tasks, there are designated inspectors, who must make a documentary and photographic record of any type of cosmetics entering or manufactured within the country, physical spaces where they are made or utensils that are used for the same purpose. A protocol is also established for taking samples of the products and detailed regulations regarding the labeling and sale of products in the cosmetic area. (25)

This same document also specifies that, in order for a product to be accepted for sale in Canada, a list of the ingredients used must be provided and all ingredients must be approved by The Food and Drug Regulations and The Natural Health Products Regulations. There is also a list of requirements designed for certain types of specific cosmetic products such as hair dyes, deodorants or products that are composed of specific ingredients. (25)

h) Nigeria

In the African country Nigeria, the regulations established by NAFDAC (National Agency for Food & Drug Administration & Control) are applied, specifically by the DER (Drug Evaluation & Research Directorate). These Good Manufacturing Practices (GMP) were written in 2018 and are focused on cosmetic products. In this sense, the norm called DER-GDL-004-00 has 19 chapters, among which are its scope, general considerations, personnel, organization, qualifications and responsibilities, training, premises, storage areas, equipment, hygiene and sanitation, production, quality control, documentation, internal audit, external contracts and analysis, complaints and claims, terms and definitions, and finally, bibliography. This standard serves to ensure that cosmetic products are produced in a manner consistent with quality standards. In Nigeria, no product may be manufactured, stored or marketed unless it complies with the guidelines set out in the regulations. It should be noted that these guidelines do not cover

aspects of personnel safety or environmental protection. (26)

On the other hand, a study published in 2015 studied the exposure to metals in creams in Nigeria, in order to assess the safety of using these in this population. Unusual levels of lead and cadmium were detected, particularly in skin gloss creams, indicating that the standards currently applied are not effective in regulating this quality characteristic in products placed on the market. (48)

i) Latin America

In Venezuela there is a Manual for Good Manufacturing Practices for Cosmetic Products by CAVEINCA, which is prepared by the Ministry of Health and Social Assistance of the Republic of Venezuela, seeking to guarantee the quality of cosmetics and drugs in each of their manufacturing stages. This manual consists of nine chapters and an annex, which applies to all cosmetic manufacturing companies in Venezuela, in order to ensure compliance and identify deficiencies in the processes. The chapters cover personal organization and hygiene, documentation requirements, standards related to premises, equipment, manufacturing processes, preparation and packaging, warehouses, quality control and maintenance and services. (27)

In Colombia, cosmetics producers can be certified with the health authority INVIMA, voluntarily, by Resolution 3774 of 2004, through the Good Manufacturing Practices, with the certifying body of ISO 22716:2007. (28) In addition, the members of the Andean Community of Nations (CAN), in order to harmonize internal legislation on cosmetic products, created Decision 516, 2002, in which they adopted the Harmonized Technical Standard for Good Manufacturing Practices for Cosmetics, which is mandatory to opt for the certificate of production capacity. (29)

Comparison between regulations

As has been shown, most of the regulations applicable to the different countries contain basically the same guidelines, specifications and issues to be addressed, as they cover quite similar topics. In addition, the fact that they are regulations that specify requirements that could affect human health, it is evident that the greatest possible standardization is being sought. To exemplify this, the following is a comparison between the most widely used regulations worldwide, which are the European and the United States.

European and U.S. regulations have flexible provisions for the introduction of new products because they rely on producers to verify the safety and testing of their products, rather than on a government licensing system or market review, and there are expert committees that provide recommendations of safe ingredients for use in cosmetics. In addition, there are requirements for labelling information, including ingredient declarations and instructions for use, as well as lists of certain ingredients that are prohibited for use in cosmetics. (49)

Both regulations provide a high level of product safety and quality, which is achieved without imposing unnecessary mandatory regulations, which could lead to obstacles to the introduction of new products for customers. (50)

4. Conclusions

It is important to note that basically all regulations, rules and standards specify the same requirements to meet the needs of the customer, and at the same time, meet the safety and quality of a product that will circulate both in domestic and international markets. In this sense, it is clear that the most widely used standard worldwide is ISO 22716:2007, which is widely disseminated across all continents, and is used as the basis for many of the national regulations implemented in countries. The changes made by local regulations are minimal to the content of the standard, adding some clauses to it, but leaving its basic structure intact.

Given that all the regulations studied have the same objective, which is to safeguard the integrity of customers in different markets, by applying requirements to the products, it is clear that they all have the same purpose, with slightly different paths. The aspects that most of the standards cover are quality in the laboratories, physical, chemical and microbiological analysis, product integrity, product handling, raw materials and distribution, procedures and records, as well as the facilities where they are manufactured.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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