



Public Understanding of Chemistry: Chemistry and its social-political-economic context continue to change.

Chemistry and chemistry-based technology that impact our lives make for the complexity and controversy of life and set the stage for thinking about public understanding of chemistry. The Public Understanding of Chemistry section will try to address chemistry in real life context with original contributions (articles/position papers/policy briefs) and/or published articles and columns in reputable sources (used with permission).

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THE MAKE UP OF YOUR MAKEUP

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Introduction

The manuscript is adapted from *The Make Up of Your Makeup* seminar that was originally presented at the #girlSTEM Conference on May 22, 2014 at Delaware Valley College in Doylestown, Pennsylvania. #girlSTEM seeks to inspire middle-to-high school girls in Bucks County, Pennsylvania to pursue Science, Technology, Engineering and Math (STEM) related fields. #girlSTEM features a variety of interactive seminars with professional women, hands-on workshops, and open forum discussions. This session explored making products with the young women based on a concept that was presented to their team using their knowledge from a list of ingredients and information about each of those ingredients. The attendees of #girlSTEM had an opportunity to explore the cosmetic industry from a drug development perspective in a way that engages them to dig deep into their purses and minds to examine what goes into the products that women use on the largest organ – their skin.



Abstract

The Quality by Design approach implemented in the drug development process is described by comparison to the intricacies of skin and cosmetic products as a framework for the manuscript. The interrelated aspects of material selection, process controls and product specification are discussed as they relate to the targeted product profile. The seminar encouraged the students to look closely at the materials that constitute the skin and cosmetic products they frequently use and the intended purpose of the ingredient to achieve the desired product functionality and attributes.

Key Words

STEM, Makeup, Quality by Design, Drug Development

The *Make Up of Your Makeup* is a high level perspective of how products for the skin are created and what role the ingredients play in meeting the intended product concept.

Discussion

Let us first take a look at how beautiful the skin is! Look around. The skin is not just the covering of our bodies, it is a working organ. The layers of your skin have individual functions as well as collaborative functions that help with defense, healing and internal controls. The skin has the innate response by the cells present to recognize and destroy foreign microbes. It is wonderful knowing that when you cut yourself, you can put a bandage over the cut and let your skin take care of the rest.

Since we are all scientists here, I am assuming that you are thinking the same questions that I am about the skin. If the skin performs all of these miraculous functions, why do we need beauty and drug products?

My response to that question is: since the skin is such a complex organ, there are so many different things that can possibly go wrong. That is why it is a challenge and there are countless opportunities to provide treatments.

For example, wound healing can be affected by several factors such as age, health and immune status. Typically, when we think of illnesses we consider those where a function is not working properly and therefore cannot fight disease or infection which can be described as hyporeactive immune response. There are a plethora of implications that are a response to excessive healing. Wound healing, particularly excessive wound healing as seen in eczema patients, can also be impacted by the interplay between genetics and environmental factors [1] to create a hyperreactive immune response for the patient. The drugs that are currently available for eczema function by slowing down the immune response of the patients to achieve the skin's normal ability to heal itself.

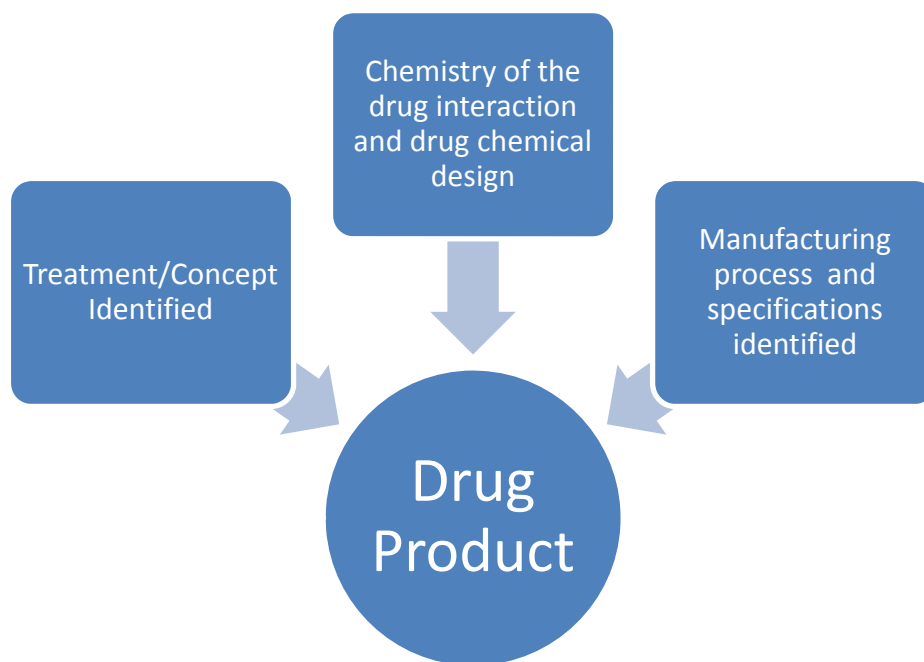


Figure 1. Overview of Drug Product Development Formulation Target Profile

The skin conveys inner health. There is a real connection between what's going on inside and outside the body. It is not really magic but rather that skin demonstrates some conditions that are going on inside the body to the outside of it. A skilled dermatologist can recognize the patient's disease status based on the manifestation of skin conditions [2].

In the context of this presentation, the general understanding described about the drug development focuses on the process which begins with an idea. A concept that is typically brought to the team and from that idea,

based on their knowledge of the mechanisms of the body, pharmaceutical chemistry, manufacturing and regulations, the team collaborates to create a project plan. The plan will move forward in the form of a compound (or multiple compounds) and manufacturing scheme that is identified to be tested clinically (Fig. 1). The goal of the team working together throughout the duration of the project is to design quality into the product through all aspects of drug product design. Once the formulation and process are found to be acceptable, the team will seek approval from the corporate leaders and the FDA to market the product.



The aim of pharmaceutical development is to design a quality product and its manufacturing process in order to consistently deliver the intended performance of the product. The information and knowledge gained from pharmaceutical development studies and manufacturing experience provide scientific understanding to support the establishment of the design space, specifications, and manufacturing controls [3].

There are a few ways the drug development team can approach the proposed drug concept. Again, the team will ask questions. What is currently in the market that can effectively treat the patient? Is there a drug product that exists that may currently treat the indication or a similar indication? Understanding the disease and specifically targeting indication as well as the pharmacology of the drug product and excipients is critical to the success of the development program.

Since many diseases currently have treatments which are clinically shown to be effective, drug development teams also look at the challenge in a different way. Can the drug currently in the market be improved? In the case of a painful skin condition, patients typically prefer a dosage that can be applied without causing the affected areas to itch or burn. Optimizing the application, excipients and dose of the product for this type of patient could potentially increase their quality of life.

When considering the formulation of the product for the proposed concept, the pharmacokinetics and pharmacodynamics must also be considered. If a product is being designed to treat a skin indication, the state of the skin is critical. If the skin is broken at the time of application, the route of dosing the product and other physical attributes become critical to the quality of the product.

For the product to work properly and for the patient to benefit from the product, the target product profile will be established by the development team. The team will choose raw materials based on the purpose of the product and known excipients for the type of formulation using the Inactive Ingredient search tool provided by the Federal Drug Administration [4].

Once the formulation is finalized and has been shown to meet all of the critical specifications for the product, the manufacturing process is validated and scaled appropriately. To seek approval from regulatory authorities to market the product to patients, the established process to execute the concept flawlessly and ensure that it is reproducible and maintains the specifications over time must be determined.

Summary and Recommendations

The students that participated in the #girlSTEM conference seminar were offered a unique perspective of

drug development using makeup as a mechanism to establish a direct connection to products the young women use every day. The young women were encouraged to look at the labels of their own skin products and evaluate the ingredients while using naturally derived ingredients to meet a target product profile in a hands-on activity. The young women were strongly encouraged to look differently at their skin and the products they use by applying their education and experience to reevaluate their definition of beauty and become strong women through mind, body, and spirit.

References

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