



Beautiful Translations: Foundations for the Personal Care and Cosmetics Industry

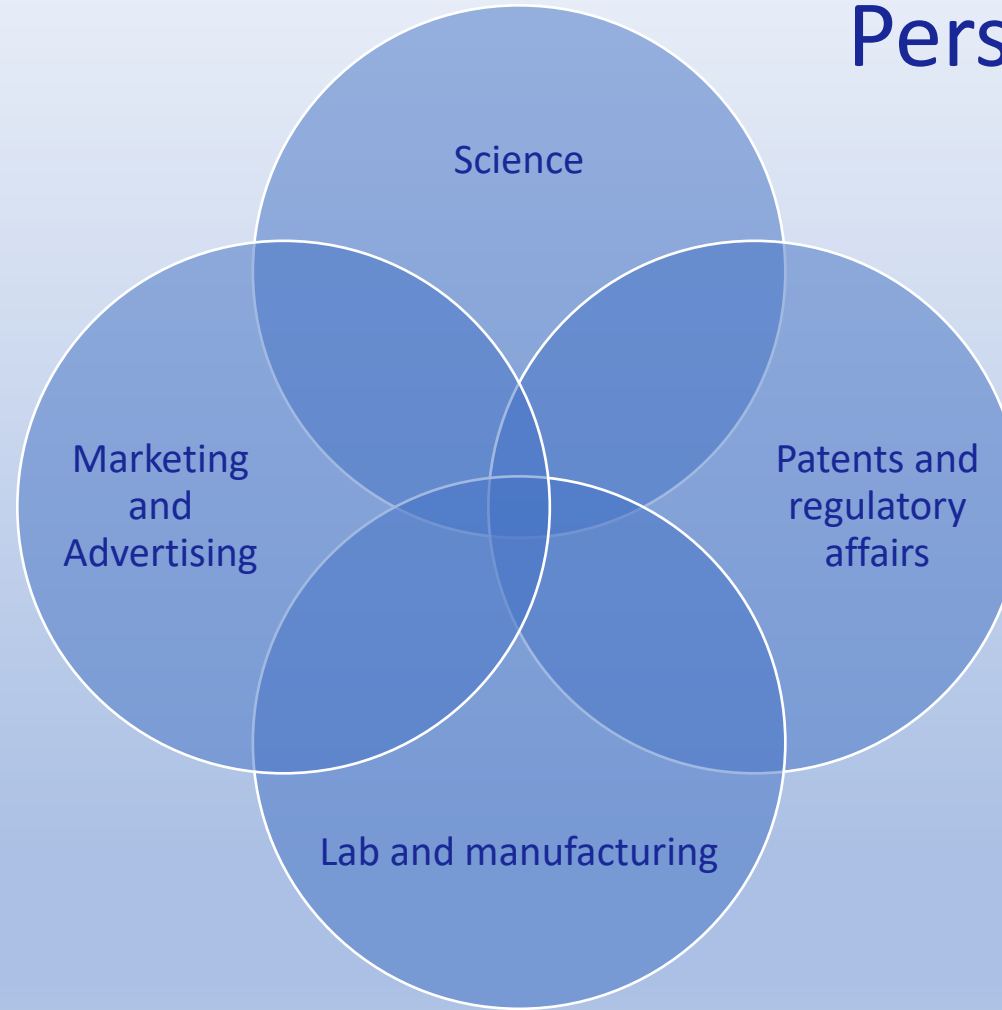
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@ChemXlator



The Beauty Business

The Personal Care Business



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Related areas



Regulatory framework

- Understand the rules

Scientific and Technical Assessment

- Understand the technical fields

Ingredients

- Understand the chemistry and engineering

Marketing

- Understand the hype



Regulatory Framework

Understand the rules

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Regulatory Regions

- Influential markets
 - USA + Canada
 - EU (followed by Russia, LatAm and ASEAN)
 - Japan
 - Korea (increasingly aligned with EU)
 - China

Regulatory Differences

- Pre-market registration for cosmetics vs. light notification and in-market control
- Labelling requirements: lack of recognition of the International Nomenclature Cosmetics Ingredients (INCI)
- Non-harmonized system of forbidden/restricted/positive lists of ingredients
- Animal testing: non-acceptance of alternative methods
- Non-harmonized definition of a “cosmetic product”

Hazardous to Health?

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REMEMBER: WE'RE USUALLY TALKING ABOUT CHEMICALS










HCS PICTOGRAMS & HAZARDS		
Health Hazard  <ul style="list-style-type: none">• Carcinogen• Mutagenicity• Reproductive Toxicity• Respiratory Sensitizer• Target Organ Toxicity• Aspiration Toxicity	Flame  <ul style="list-style-type: none">• Flammables• Pyrophorics• Self-Heating• Emits Flammable Gas• Self-Reactives• Organic Peroxides	Exclamation Mark  <ul style="list-style-type: none">• Irritant (skin and eye)• Skin Sensitizer• Acute Toxicity (harmful)• Narcotic Effects• Respiratory Tract Irritant• Hazardous to Ozone Layer (Non Mandatory)
Gas Cylinder  <ul style="list-style-type: none">• Gases under pressure	Corrosion  <ul style="list-style-type: none">• Skin Corrosion/ burns• Eye Damage• Corrosive to Metals	Exploding Bomb  <ul style="list-style-type: none">• Explosives• Self-Reactives• Organic Peroxides
Flame over Circle  <ul style="list-style-type: none">• Oxidizers	Environment (Non-mandatory)  <ul style="list-style-type: none">• Aquatic Toxicity	Skull & Crossbones  <ul style="list-style-type: none">• Acute Toxicity (fatal or toxic)

Image taken from <http://www.fireengineering.com/articles/2013/07/globally-harmonized-system-what-is-it.html>

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Examples:

- Depilatories and hair straighteners are highly alkaline and can cause burns
- Shampoos and conditioners are eye irritants
- Imagine a baby swallowing lots of baby powder

READ ALL ABOUT IT:
Cosmetic Safety: More
Complex than at First
Blush

Drugs or Cosmetics?

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Cosmetics in the USA

*“articles **intended** to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise **applied** to the human body... for **cleansing, beautifying, promoting attractiveness, or altering the appearance**”*

[FD&C Act, sec. 201(i)].

Sometimes both

- Two intended uses
 - fluoride toothpaste
 - antidandruff shampoo
 - deodorants that are also antiperspirants

Cosmetics in the EU

See handout

Solutions

- USA: Over-the-Counter (OTC) Drug Monographs
- US FDA New Drug Applications are not required for cosmetics that are also drug products **as long as** the active ingredients used fall within the bounds of one of the monographs
- EU regulations: Regulation replaces Directive
- Varies in from country to country, e.g., French pharmacy system

And complications...

- Cosmeceuticals: topical
- Nutricosmetics: oral

The Food, Drug and Cosmetics act does not recognize any such category as "cosmeceuticals." A product can be a drug, a cosmetic, or a combination of both, but the term "cosmeceutical" has no meaning under the law."

Therefore:

"Warning — The safety of this product has not been determined".

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

And then there's Soap

- In the US, soap is a special case
- The FDA defines soap narrowly, in chemical terms

READ ALL ABOUT IT:

FDA [21 CFR 701.20]



Scientific and Technical Assessment

Understand the technical fields

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Product Testing

- Quality Control testing
- Product Performance testing
- Claims Substantiation testing
- Mechanical testing



Quality Control

- Stability testing
 - Storage over time
 - Stability cycles (high and low temperature)
- Jars are the worst case

Quality Control

- Primary contamination
 - Occurs during production
- Secondary contamination
 - Comes during use
 - sponges (foundation)
 - brushes (tattoos, liners)
 - lip gloss and lipstick



Quality Control

- Challenge testing (Microbiology)
- What might not need microbiology testing?
 - aerosols
 - single-use items
 - air-free packaging

Product Performance: Skin

- End of testing on animals required innovative new techniques
- Four key measurements
 - moisture levels
 - transepidermal water loss
 - skin elasticity
 - cell turnover



Product Performance: Hair

- Tress testing
 - swatches of hair
 - treated under controlled conditions in laboratories
 - wet or dry
 - bleached, permed, colored, styled
 - measure shine, drag etc.

Claims Substantiation

- Validate marketing claims with science
- Consumer tests under controlled conditions
- Statistical analysis methods and measurement devices can be manipulated to give the results that you want to be able to use a claim – bad science is everywhere

Mechanical testing

- Container lid opening force
- Actuation force of pumps/sprays
- Hardness
- Break strength
- Consistency
- Compaction strength



Images from
www.stablemicrosystems.com



(multilingual site handy for testing terminology)



Ingredients

Understand the chemistry and engineering

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Complex manufacturing



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Active Ingredients

- Defined in the US in monographs
 - by name
 - by acceptable %
- Listed first on labels
- No such concept in the EU

Specialty raw materials

- Surfactants
- Emollients
- Polymers
- Humectants
- Colors
- Fragrances
- Preservatives
- Fillers
- Resins
- Waxes/lubricants
- Gellants
- Binders
- Fibers
- Thickeners



Preservatives

- Control of bacteria, molds and yeast
- Hot media topic
- Parabens
- How to reduce preservatives?
 - change packaging
 - reduce free water (add solutes like glycols and salts)



Marketing

Understand the hype

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A Different Skill Set

- Translating marketing and advertising texts requires a different set of writing skills
 - Beyond correct terminology
 - Creativity and flair

Market-specific knowledge

- Behavior and trends
 - Market tolerance for phosphate-free detergents
 - The desire for a suntan in the developed west versus whiter skin in the far east
 - How sustainability affects purchase

Variety

- Launch kits
- Sales pitches
- Merchandising documents
- Ad copy
- Market research questionnaires





Have a great conference!
Any questions?

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