Council
Member Briefing
September 24, 2013

Personal Care Products Council
Committed to Safety, Quality & Innovation
Lezlee Westine
President & CEO
Member Briefing

Register Today!

www.personalcarecouncil.org/2014-Annual-Meeting
UL Quality, Compliance and Learning

Presented by:
Kavita Mehrotra, Ph.D
Head, Global Strategic Alliances
Agenda

About UL: Our mission, and how we are aligned with you

Our Partnerships

Personal Care Trends

Automating the Effectiveness Cycle

Case Studies

Questions
WORKING FOR A
SAFER WORLD

Product Safety
- product safety
- market access
- regulations & standards

Environment
- environmental claims
- sustainability
- indoor air quality

Verification
- safety & quality testing
- responsible sourcing
- wireless, security, EMC
- energy efficiency

Life & Health
- medical devices
- clinical research
- water quality
- workplace health & safety
- quality, compliance, and learning
What makes the beauty and personal care industry unique?

“There is certainly no absolute standard of beauty. That precisely is what makes its pursuit so interesting.”

John Kenneth Galbraith
Renowned Economist
UL Quality, Compliance and Learning

Learning Services and Solutions that Help Companies:

- Achieve Compliance with Laws and Regulatory Standards
- Minimize Organizational Risk
- Improve Quality and Business Performance Across the Enterprise
- Educate Their Supply Chain Partners and Customers
Point to Ponder

And the day came when the risk to remain tight in a bud was more painful than the risk it took to blossom” - Anaïs Nin
Cosmetic GMP guidance is voluntary

But FDA set expectations in June 2013 as it identifies the standards and issues that can affect the quality of cosmetic products.

“FDA can inspect manufacturing facilities to determine if proper controls and practices are being followed. FDA also works with U.S. Customs and Border Protection to examine imported cosmetics.”

Source: www.fda.gov
Our Partnership with Personal Care Products Council

Leverage our platform and Personal Care Courses:

Safety Assessments -- based on Council Safety Evaluation Guidelines

Microbiology -- based on Council Micro Guidelines

GMP Courses -- based on ISO standard 22716 and Council QA Guidelines
Our Partnership with Personal Care Products Council

Eight Courses Focused on Cosmetic GMPs:

- Essentials of an Effective Calibration Program
- Failure Investigations for Cosmetic Manufacturers
- FDA Regulated Product Labeling
- Introduction to Microbiology
- Introduction to Toxicology
- Maintenance and Cleaning of Cosmetic Manufacturing Equipment
- Resolving Out of Specification Test Results
- Vendor Certification for Cosmetic Manufacturers
Our Partnership with Personal Care Products Council

- Courses take about 45 minutes to complete
- Courses include audio narration
- Courses contain quizzes to measure retention
Our Relationship with US FDA

Approximately 200 online courses developed with the Agency to standardize Investigator training:

• FDA Inspection & Enforcement Library:
  50+ courses used by FDA to train 30,000 inspectors globally

• GMP Libraries:
  90+ courses, many written by ex-FDA officials, and several courses reviewed and used FDA as part of inspector orientation

• BIMO Library (Clinical Inspections)
  7 Courses authored by FDA to train Food Inspectors

• Food Safety Library
  50+ courses used by FDA to train Food Inspectors
Training Management Best Practices:

Aligning Policies to the Five Elements of Quality Systems components:

1. Procedures
2. Process Implementation and Controls
3. Qualification
4. Documentation
5. Learning Effectiveness
ENTERPRISE-WIDE SOLUTIONS

- Learning Management Technology
- Regulatory Content
- Advisory Services
- Customizations
Personal Care Trends

Clients are reporting intensifying scrutiny

- Questioning deviations even when “in spec”
- Asking about how companies are ensuring “understanding” of SOPs, policies and training, beyond just “read and acknowledge”
- Increased frequency and intensity of FDA inspections
Industry Best Practices for Improving “Learning Effectiveness”

- Establish a “Governance” Board of stakeholders (builds organization ownership)
- Define a process to align ‘business owners’ with the right learning content
- Have a senior VP sanction/support this board.
- Content owners represent the senior level within each business unit.
- Content must remain current, consistent and appropriately aligned to the individual(s). As content is added or modified or retired, the owner or designee must approve these changes.
Automating the “Effectiveness Cycle”

Quality and Manufacturing teams should consistently capture, then measure, training effectiveness at various stages:

- Conduct Baseline assessments
- SOP Delivery and Assessments
- Online Courses
- Measure Training Satisfaction
- Capture OJT/Mentoring Events
- Conduct Post Assessments
Automating the Effectiveness Cycle

Measuring Progress via Online Assessments:

Build Baseline and Post-Training Forms:
Data is captured for analysis that demonstrate improvement

Capture Signatures from Both Employee and Trainer/Supervisor
Provides visibility for manager oversight

Auditable Format:
Record can be presented as part of Certification curricula within an employee transcript
### Case Study: Reducing GMP Training Time

**Pharmaceutical Company, 500+ employees**

<table>
<thead>
<tr>
<th>Measurement:</th>
<th>Quality Assurance Develops Own GMP Training</th>
<th>GMP Training Courses Managed by UL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standards</td>
<td>Lacks uniformity (assessments, content, style of delivery)</td>
<td>Standardized policy training (self-paced, uniform testing)</td>
</tr>
<tr>
<td>Course Development Time</td>
<td>10 hours per week to manage training</td>
<td>2 hours per week to manage training</td>
</tr>
<tr>
<td>Employee Time</td>
<td>4 hours to attend Powerpoint-driven classes (three events)</td>
<td>2 hours per week to take computer-based training (three courses)</td>
</tr>
<tr>
<td>Training Signature Process</td>
<td>4 hours to file training record completions</td>
<td>1 hour to electronically sign computer-based training course</td>
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**Reduced GMP Training Time (Development and Attendance) by 12 hours per week**
### Case Study: Moving from Paper-Based to Automation

#### Global manufacturer, 2,000 employees and contractors:

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Paper-Based Compliance Training Process</th>
<th>Training Management Via UL ComplianceWire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curricula</td>
<td>Training Requirements not defined for each job role</td>
<td>Training Matrix automated for each job role</td>
</tr>
<tr>
<td>Administration Time</td>
<td>10 hours per week to maintain paper files</td>
<td>3 hours per week to maintain electronic records</td>
</tr>
<tr>
<td>Employee Time</td>
<td>6 hours per week per employee Employees dragged into training room for ever SOP revision ()</td>
<td>2 hours per week to complete SOP training, with higher satisfaction ratings: “convenience” and “ease of use” top comments</td>
</tr>
<tr>
<td>Audit Preparation Time</td>
<td>12 hours per audit to fulfill requests from auditors for qualification and training records</td>
<td>4 hours per audit to fulfill requests from auditors for qualification and training records</td>
</tr>
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**Reduced training record-keeping by 11 hours per week**
We want you to tell us!

Beyond what we discussed, what are the topics YOU think is most relevant today?

Please write to me at:
Kavita.mehrotra@ul.com
Or
Brent Nussbaum, Marketing Director, PCPC, at:
nussbaumb@personalcarecouncil.org
Additional Questions?
Member Briefing

• INCI Update
• QAC Update
INCI Update

INCI Name for Nano

• What does it mean?
• How is it used?

Retired INCI Peptide Names

• What are they?
• How will it impact labeling?
INCI Name for Nano

- Nano will be published as an INCI Name and defined in accordance with the new EU Regulation:
  
  [Nano] is the term added as a suffix to an INCI name to identify that the ingredient meets the definition for a nanomaterial as identified by the EC Regulation No. 1223/2009.

- As a suffix, [Nano] can be applied to any INCI name that meets the definition in the new EU Regulation.

- If other jurisdictions develop nano-labeling regulations, they will referenced in the definition.

- Intent is to provide flexibility in labeling.
INCI Name for Nano

• Other monographs for “labeling terms” exist in the Dictionary, e.g., Flavor, Fragrance

  Fragrance is a term for ingredient labeling used to identify that a product contains a material or a combination of materials normally added to a cosmetic to produce or to mask a particular odor. The term may be used instead of listing the individual components of the fragrance in accordance with U.S. 21 CFR 701.3(a). The labeling name in the EU will be Parfum under the 6th Amendment to the EC Cosmetics Directive.

• The responsibility of verifying that ingredients meet the EU definition for nano rests between the ingredient supplier and marketing company
Retired INCI Peptide Names

- Two peptide ingredients with a long history of usage have recently been revised:
  - Palmitoyl Oligopeptide
  - Myristoyl Glycine/Histidine/Lysine Polypeptide
- Definitions for these ingredients have been revised to include sequence information to facilitate upcoming CIR review
# Retired INCI Peptide Names

<table>
<thead>
<tr>
<th>Retired INCI Name</th>
<th>Current INCI Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myristoyl Glycine/Histidine/Lysine Polypeptide</td>
<td>Myristoyl Tripeptide-1</td>
</tr>
<tr>
<td>Palmitoyl Oligopeptide</td>
<td>Palmitoyl Tripeptide-1, Palmitoyl Hexapeptide-12</td>
</tr>
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</table>

Retired INCI Peptide Names

• Because of historic usage of these names, both the old and the new names will be published for an interim period to accommodate updating product labels and technical literature.

• Marketing companies may continue to label with the original nomenclature until economically feasible to reprint.

• Original names will include the term “Retired” in the monograph title.

• The Introduction to the Dictionary will contain a section to describe retired names.
MYRISTOYL GLYCINE/HISTIDINE/LYSINE POLYPEPTIDE (RETIRED)

INCI Monograph ID: 10681
Definition: Myristoyl Glycine/Histidine/Lysine Polypeptide is the product obtained by the reaction of myristic acid with a tripeptide consisting of gly-his-lys.

The INCI Name, Myristoyl Glycine/Histidine/Lysine Polypeptide, originally developed in 1997, was designated with a retired status in 2013. Trade name assignments formerly published with the name Myristoyl Glycine/Histidine/Lysine Polypeptide will be retained in the retired monograph, and also published with the new name assignment, Myristoyl Tripeptide-1 (q.v.), for an interim period. For further information, consult the Introduction, Retired INCI Names.

Chemical Class: Peptides
Reported Function: Skin-Conditioning Agent - Miscellaneous
Ingredient Sources: Animal; Plant
Technical/Other Name: Myristoyl Tripeptide-1
Trade Name Mixture: Myristyl-GHK (Sederma)
MYRISTOYL TRIPEPTIDE-1

INCI Monograph ID: 28449
Definition: Myristoyl Tripeptide-1 is the product obtained by the reaction of myristic acid and Tripeptide-1 (q.v.).

Chemical Class: Peptides
Reported Function: Skin-Conditioning Agent - Miscellaneous
Ingredient Source: Synthetic
Technical/Other Name: Myristoyl Glycine/Histidine/Lysine Polypeptide (Retired)
Trade Name Mixture: Myristyl GHK (Sederma)
Misc.

  - Contains approximately 1900 new INCI names
  - VCRP data, Japanese translations, CAS numbers, and cross-reference sections have been updated, e.g., UNII Codes, EU Annexes, DSD, etc.

- INCI Polymer Names/REACH List
  - Contains INCI names in three polymer-related chemical classes: synthetic polymers, carbohydrates biological polymers, with related CAS, monomers (where possible) and supplier info
• INCI/Polymer names list available soon in the InfoBase

• Non-subscribers can contact Natasha Clover, clovern@personalcarecouncil.org
Misc.

• Available soon also to the InfoBase will be periodic updates to CAS info and related INCI, (e.g., new CAS, deleted CAS)

• New Science Staff Member:
  KATRIKA SHAW | Cosmetic Chemist
  The Personal Care Products Council
  1101 17th St., NW, Suite 300, Washington, DC 20036
  202-454-0351 | shawk@personalcarecouncil.org
QAC Update

• FDA Draft GMP Guidance
• Supply Chain Integrity Webinar
• Fall Quality Workshop/Science Symposium
FDA Draft GMP Guidance

- Reflects FDA’s effort to harmonize cosmetic GMPs to ISO 22716 Cosmetic GMPs as noted in the 2007 ICCR agreement
- QAC recently completed an analysis of the Draft Guidance which included a comparison with ISO 22716
QAC acknowledges FDA’s support to internationally align cosmetic GMPs.

FDA’s effort shows recognition of the many worldwide GMP experts that contributed to the endeavor.

Closer analysis of the Draft Guidance revealed the omission of several important GMP elements from ISO 22716, e.g., sections on OOS, Waste Management, Pest Control, Subcontracting.
FDA Draft GMP Guidance

- Additional prescriptive language included in the Draft Guidance, e.g.,
  - Returns to be evaluated for conformance to specs
  - Buildings should have adequate ventilation complete with bacteriological controls
  - Water system should routinely be sanitized to prevent biofilm
  - Weighing and measuring of raw materials should have a second signature signoff
FDA Draft GMP Guidance

- In comparison to the 2008 checklist
  - New section on water added
  - Expanded section on complaints specific to adverse events
  - Table of prohibited ingredients
  - Omission of reference to VCRP and ingredient labeling
Supply Chain Integrity Webinar - Delivery & Handling of Bulk Chemicals

• Webinar Part I – September 18, 2013
  • Procurement requirements – procedures & systems
  • Tanker Truck vendor requirements
  • Tank Wash procedures

• Webinar Part II – October 2, 2013
  • Chemical Supplier – procedures & systems
  • Manufacturing plant – procedures & systems

http://www.personalcarecouncil.org/science/supply-chain-integrity-how-manage-delivery-and-handling-bulk-chemicals
2013 Science Symposium

http://www.personalcarecouncil.org/live-meeting/2013-cosmetic-science-symposium
2013 Science Symposium

• **Wednesday, October 23, 2013**
  Safety Assessment Workshop
  Environmental Workshop
  Exhibitor Reception

• **Thursday, October 24, 2013**
  Quality Workshop
  Microbiology Workshop

• **Hotel Information: Newark Airport Marriott**
  Room Rate $179++ per night
  Cut off Monday, October 7, 2013
  973-623-0006
2013 Science Symposium/Quality Workshop

Theme: The Impact of Human Error in Quality

The Impact of Human Error on Quality (Keynote), Ginette Collazo, Human Reliability Consultancy

Human Error: Case Studies, Steve Greer, P&G

Human Error: A Perspective on CAPA/Root Cause/Change Control, Ken Peterson, Master Control

FDA Regulatory Update, Karyn Campbell

Health Canada Regulatory Update

Quality Metrics: A Performance Improvement Tool, Tom Hines, Amway and Joe Bonina, L’Oreal

Speaker Roundtable
CONTACT INFORMATION

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Director, Cosmetic Chemistry
Personal Care Products Council
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Farah Ahmed
Associate General Counsel

Legal & Regulatory Update
Member Briefing

Sunscreen Update

• On September 4, 2013, PCPC submitted comments to CDC new docket requesting information regarding on opportunities and actions that can be taken by entities, including industry, to reduce exposure to UV radiation by raising awareness of proper UV avoidance practices.

• CDC indicated it will be working with the Surgeon General on this issue.
Member Briefing

Sunscreen Update

• PCPC efforts advocating for antiaging and skin cancer prevention claims on sunscreen labels
• Outreach/education efforts with dermatology community
• Public education, including Skin Smart video series
Sunscreen Update

• We believe individuals of all ages and skin tones should use sunscreens every day as part of an overall safe sun regimen to reduce the risk of UV damage, including premature skin aging and skin cancer.

• As we continue to advocate for sound science, we look forward to participating in CDC and the Surgeon General’s efforts to prevent skin cancer and save lives.
Member Briefing

FDA/Sunscreens

- Nothing new...
  - Final Labeling and Effectiveness Testing Rule
  - SPF 50+: still a Proposed Rule
  - Dosage Form: still an Advance Notice of Proposed Rulemaking
  - TEA’s: still waiting (next step is expected to be a Proposed Rule)
CONTACT INFORMATION

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Member Briefing

Council Annual Meeting | February 23 to 26

Enhanced Speaker Line Up

• Tony Hsieh, CEO, Zappos, will open up the meeting as keynote speaker for the Sunday evening Welcoming Dinner.

• Jonah Berger, Wharton marketing professor and author of bestseller “Contagious,” will Keynote the Monday plenary session.

• Rana Faroohar, Columnist, TIME; Global Economic Analyst, CNN, will Keynote the Wednesday plenary session.
Continue Global Focus and Add Communications Content

- Lisa Powers along with the Communications Executive Committee will develop a panel for the Tuesday plenary session and working to secure a keynote speaker.
- Wednesday Plenary session will focus on global collaboration and strategies.
- Francine Lamoriello along with the International Executive Committee will develop additional content for the Global plenary session.
Council Annual Meeting | February 23 to 26

Ensure Ample Time for Business and Committee Meetings

• Each plenary session will end by 11:30 to open up the afternoon for breakout meetings, strategic appointments, and other business activities.

• Tuesday evening is now an open night to allow publishers and other groups to host private dinners.

• Sunday prior to the Welcome Dinner and Wednesday after the Plenary session are open for Committee meetings.
Ensure Programming and Value for Associate Council Members

- We will be reaching out to the publishers to help construct a panel on mobile commerce or similar content.
- We will be working with Council supplier members to develop a panel on issues shared by the finished product and supplier community.
- Tuesday will feature plenary and breakout sessions targeted to the R&D and Supplier communities.
Register Today!

www.personalcarecouncil.org/2014-Annual-Meeting
CONTACT INFORMATION

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