# Regulatory Essentials - November 24, 2021

# Cosmetics Alliance Fall Virtual Regulatory Workshop – Register Now!

Regulatory Workshop Details:

Date: December 9, 2021

Time: 8:30 am - 12:30 pm EST

**Location:** Virtual

Cost: \$350 (including Member Engagement Session)

\$50 off for all additional attendees from the same member company

### Preliminary Agenda

Member Engagement Session:

Date: December 10, 2021

**Time:** 9:00 am - 11:00 am EST

**Location:** Virtual

Get ready for our Fall Virtual Regulatory Workshop on December 9-10, 2021. Cosmetic Alliance Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business. You also do not want to miss the Member Engagement Session the next day to discuss what was heard the day before with your industry colleagues and CA Staff.

Price of the workshop is per login; attendees can not share logins.

#### Cancellation Deadline

Registration fees will be refunded in full for cancellations received before November 26, 2021. Cancellations received after November 26, 2021, will not be refunded. Substitutions permitted at any time from the same company.

#### Register

### **Health Updates**

# Important Developments for Manufacturers that Export to China

### WHAT YOU NEED TO KNOW:

Quebec and Ontario Agree to Issue Interim GMP Certificates For Cosmetic Exports to China

As you may know China recently introduced an exemption to their regulatory requirements for animal testing on imported cosmetic products.

To qualify for this exemption exporters, need to provide a government issued certificate of GMP compliance. Certificates must be provided for sites in which cosmetic products are manufactured and must be specifically issued by a government authority in the countries from which the product is manufactured.

The challenge with this requirement is that that there are very few jurisdictions around the world (if any) where such certificates are issued by government. CA has been working with Health Canada as the regulatory authority to establish a process to support the issuance of such a certificate.

Although we expect Health Canada to shortly approve such a certificate, trade/economic ministries in both Quebec and Ontario have agreed on an interim basis to issue a certificate with respect to GMP compliance for cosmetic exports to China.

These certificates are intended for facilities in their respective jurisdictions that:

- Manufacture cosmetic products and have an ISO Certification (from auditors/certifiers accredited by Standards Council of Canada); and/or
- Manufacture cosmetic-like Natural Health Products and hold a Site License (SL); and/or
- Manufacture cosmetic-like drug products and hold a Drug Establishment License (DEL).

CA can help you prepare the necessary documentation and submit an application to the appropriate government office in each province. Please contact CA for further information.

### **FURTHER CONSIDERATIONS YOU NEED TO KNOW:**

- Quebec-issued certificates have been accepted by Chinese authorities (with a few shipments leveraging this certificate being cleared for import into China without animal testing)
- There is not yet a precedent for the certificate from Ontario being accepted; however, this certificate leverages the approach used in the Quebec-issued certificate
- All of these provincial-issued certificates are intended as an interim option for consideration as we finalize a more appropriate and thorough solution with Health Canada
- Overall, despite the success with a Quebec issued certificate, none of these certificates are guaranteed, as Chinese authorities have yet to make clear what specific information and supporting evidence they will accept on a consistent and long-term basis.

### WHAT YOU NEED TO DO:

If your site holds a valid ISO Certificate, SL and/or DEL, contact your CA Canada Certificates Team to explore these opportunities in further detail.

Should your company manufacture cosmetics for export to China in another Canadian province or territory, please advise CA and we will pursue a similar interim certificate in that jurisdiction.

#### Contact Info:

Deborah Kwinter, Manager, Export Certificates Program

Email: <u>dkwinter@cosmeticsalliance.ca</u>

Phone: 905 580 1400

# Quarterly Consumer Product and Cosmetic Reports Summary - Q1 2021-2022

Industry is required to submit reports to the Consumer and Hazardous Products Safety Directorate when they become aware of an incident related to their consumer product. Consumers report concerns about consumer products and cosmetics on a voluntary basis.

Percentage of industry reports and consumer reports: 64% and 36%, respectively.

Not every report the Consumer and Hazardous Products Safety Directorate receives involves an injury. Over the time period, injuries, including deaths, were reported in 32% of reports received.

242: Number of reports involving an injury

Top 3 Injury Types

Burns: 48Irritations: 44Cuts: 35

### Full Report

# Request for feedback: Modernization of the Regulation of Clinical Trials

Health Canada has reached out to Cosmetics Alliance for member feedback on the Natural Health Products Clinical Trial Transparency initiative with four short questions for stakeholders in the clinical trial space.

Health Canada is seeking to gain further insight into how the clinical trial proposals relating to transparency may positively or negatively impact research in the natural health products sector in Canada. Please answer the following questions based on your **usual practices for natural health product clinical trials in particular**. Upon completion, please email your feedback to: <a href="mailto:nnhpd.consultation-dpsnso@hc-sc.gc.ca">nnhpd.consultation-dpsnso@hc-sc.gc.ca</a>. If you have any questions or concerns, please reach out to your CA Regulatory Team at regulatory@cosmeticsalliance.ca

More details on the proposals can be found in the <u>Clinical Trials Modernization: Consultation Paper</u>.

Questionnaire EN/FR