



2020 AAHP Summit & Industry Reception/ Award Presentation

Sept. 23, 2020



Today's Speaker Line-up

12:45 p.m. ET / 9:45 a.m. PT

- Summit Welcome

1 p.m. ET / 10 a.m. PT

- Overview of Developing Guidelines
Emily Bibak, PhD, VP, R&D, Hyland's

20-minute break



Today's Speaker Line-up

2:15 p.m. ET / 11:15 a.m. PT

- Guideline Development
Adam Grobin, Independent Consultant

20-minute break

3:30 p.m. ET / 10 a.m. PT

- Francis Godwin, MBA
Dir., Office of Manufacturing Quality
FDA/CDER/OC
Q&A & Conclusion



AAHP Semiannual Membership Meeting

Next Wed., September 30, 2020

Noon ET • 9:00 a.m. PT

First Hour: Government and Industry Updates

Second Hour +: New Consumer Outreach Campaign!

Contact Info@AAHP.Info for Zoom link.



2021 AAHP Projects

- Engage with FDA: Regulatory pathway for homeopathic drugs.
- Continue to educate Congress on AAHP's comments to FDA.
- Enforcement to Compliance: Compliance through Education; Close technical gaps; Third-party audits.
- Energize and educate the retailer environment; Establish AAHP as regulatory authority thru AAHP Industry Reception.
- Consumer outreach
- Increase membership, focusing on top 80 companies registered with FDA.



Legislative & Regulatory Projects

- Engage with FDA: speaking engagements, informal conversations, meetings.
- Prepare industry for FDA/FTC enforcement: compliance training, third-party audit program.
- Educate Congress on AAHP's comments to FDA.



FDA Engagement



Donald Ashley, J.D.

Director

CDER's Office of Compliance

Video Conference
with AAHP

June 26, 2020



Francis Godwin

Director

CDER's Compliance Office of
Manufacturing Quality

Keynote speaker at AAHP's
Summit: Implementing HPUS
Guidelines for FDA Compliance

Sept. 23, 2020



FDA Outreach

Janet Woodcock

Director of FDA's
Center for Drug
Evaluation and Research

Temple University
October 2019



Homeopathic GMP Awareness Program



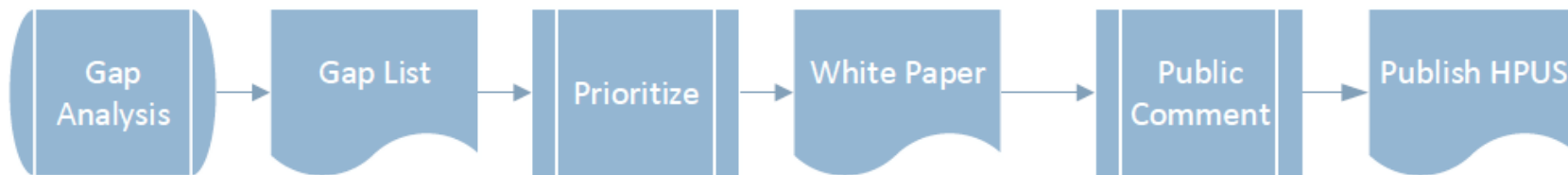
Audit Checklist 1

Question	Instructions/Questions
	Note any exceptions and comments in notebook
1.0	General Controls
	Does the facility and its many departments (organizational units) operate in a state of control as defined by the GMP regulations?
1.1	Organizational & Management Responsibilities
1.101	Does this facility/business unit operate under a facility or corporate quality policy?
1.102	§211.22(a) Does a Quality Assurance unit (department) exist as a separate organizational entity?



Stimulating Compliance

AAHP Summit: Implement HPUS Guidance for FDA Compliance



Address 5 Technical Gaps

1. Active pharmaceutical ingredients
2. Product release
3. Validation of dilution process for preparation of Hahnemannian liquids
4. Validation of dilution process for powders
5. Dosage form manufacturer—discrete solid oral dosage forms

HPUS Guidelines to Close 5 Gaps

#1: Active Pharmaceutical Ingredients (API)

Requiring detailed guidelines for APIs such as starting materials, active drug substances, intermediate and high dilutions in powder or liquid form, to ensure the material received is in compliance with the recipient's expectations and applicable regulatory requirements. The objective is the production of a guideline / whitepaper encompass the topics listed under 21 CFR 211 Subpart E-Control of Components and Drug Product Containers and Closures



HPUS Guidelines to Close 5 Gaps

#2: Product Release

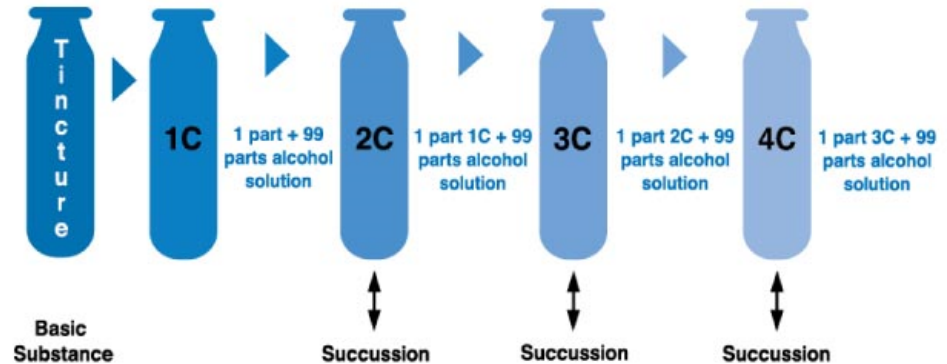
Requiring the development of a guideline for appropriate laboratory testing of satisfactory conformance to final specifications for drug products, with consideration to starting material diminishing during many attenuation steps, resulting in very low concentration of the analyte in homeopathic products. The objective is a guideline / whitepaper encompass the tests to be universally considered (identity, assay, impurities, and microbiological quality).



HPUS Guidelines to Close 5 Gaps

#3: Validation of Dilution Process for Preparation of Hahnemannian Liquids

Requiring the development of a guideline to describe the requirements for validation of Dilution Process used in manufacturing liquid homeopathic products, establishing validation procedures by groups where the groupings would represent similar chemical structures and similar manufacturing conditions. The outcome will be a guideline / whitepaper defining Hahnemannian liquid dilution process procedure steps, variables, and controls necessary to establish the process within a state of control.



HPUS Guidelines to Close 5 Gaps

#4: Validation of Dilution Process for Powders

Requiring the development of a guideline to describe the requirements for validation of Dilution Process used in manufacturing powdered homeopathic products, resulting in a guideline / whitepaper defining powder dilution process procedure steps, variables, and controls necessary to establish the process within a state of control.



HPUS Guidelines to Close 5 Gaps

#5: Dosage Form Manufacture— Discrete Solid Oral Dosage Forms

Requiring the development of a guideline to establish the Blend Uniformity (BU) and Content Uniformity (CU) requirements during the manufacturing of homeopathic drug products, including requirements for bulk hold study and powder segregation. A guideline / whitepaper defining procedures for BU and CU requirements during manufacturing homeopathic products will be produced.



Congressional Outreach

AAHP Legal Counsel
and AAHP Lobbyist
met with 80
Congressional offices.
2018–2019



Congressional Outreach

AAHP educates
U.S. Representative
John Curtis
(R-Utah-3rd District)

December 2019



Congressional Outreach

AAHP meets with
U.S. Representative
Mary Gay Scanlon
(D-PA-5th District)

Life Sciences PA event
October 2019



Congressional Outreach

Ask your federal, state or local representatives to tour your facility, meet local voters, and learn about a local business!

Health staffer for U.S. Representative Chrissy Houlahan (D-PA-6th District) visits Boiron, November 2019



AAHP Outreach to Allies



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Hear Industry News First

What does it mean specifically to the homeopathic industry?
Follow and share with your accounts!

Facebook.com/TheAmericanAssociationOfHomeopathicPharmacists

Twitter.com/TheAAHP

LinkedIn.com/Company/AAHP



AAHP Newsletter: Top 10 Articles

1. COVID-19 CARES Act Aids Availability of OTC Products
2. AAHP Supports CDC Recs on COVID
3. AAHP Views on FDA Draft Guidance
4. The Amazon Deal You Never Heard Of
5. State of Homeopathic Medicines at Retail
6. The Anatomy of a Compliant Homeopathic Label
7. Summit Photos: Experience the Excitement
8. Retail in the COVID-19 Pandemic
9. A Guide to Homeopathic Substantiation: Making Label Claims Compliant with FDA & FTC
10. 2019 Reawakening

NETWORK NEWSMay 2020



Is the Homeopathic Industry Underinvesting in Quality Systems?
Mark Land, AAHP President

From 2015 and 2018, the FDA inspected over 140 homeopathic manufacturers' sites and found that quality systems had the most problems.

This begs the question: is our industry underinvesting in quality and laboratory

The Anatomy of a Compliant Homeopathic Label
Eric L. Foxman, R.Ph., AAHP Secretary

What are the components of a compliant homeopathic drug label? How can you ensure you're meeting the requirements mandated by the FDA while still providing all the pertinent information for interested consumers?



Trade Press Awareness

Ensuring quality for homeopathic products

By Mark Land, AAHP and Boiron - 04/25/2019

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The growing number of homeopathic products sold in the drug channel has captured the attention of many retailers and others. As the demand for less processed products in all categories likely is to continue and grow stronger, it is doubtful that the resurgence of this 200-year-old system of medicine known for its safety profile is merely a trend. Indeed, it may be a new beginning.



AAHP's industry summit set for June

03/18/2019

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The American Association of Homeopathic Pharmacists will hold its inaugural summit focusing on challenges and solutions in quality and safety of homeopathic drug products, in Baltimore on June 27 and

Wegmans wins integrative medicine award at AAHP Summit

By David Salazar - 07/12/2019

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Wegmans Food Markets recently was honored at the American Association of Homeopathic Pharmacists' Summit on Challenges and Solutions in Quality and Safety of Homeopathic Drug Products. The chain took home the AAHP's Integrative



Pink Sheet

Informa Pharma Intelligence

Chain Drug Review



THE SHELBY REPORT
Your Source for Grocery News and Supermarket Insights

DRUG STORE NEWS
dsn

MMR
MASS MARKET RETAILERS

RETAIL NEWS SUPPLIER NEWS PEOPLE MONEY OPINION TOPICS LATEST ISSUES - VIDEOS

AAHP celebrates growth of homeopathy

July 10, 2019 by MMR

PRINT

PDF

EMAIL

The Voice of the Homeopathic Industry Since 1923



and CEO Scott Melville

and its inaugural industry summit
ages suppliers face in engaging

Wegmans Receives AAHP Integrative Medicine Award

July 15, 2019 2 Min Read



AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS
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Increase Retailer Awareness

Thank you
The Emerson Group
for your support!

Chain Drug Store ad
February 2020



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AAHP Outreach to Retailers

- **MMR** People Making a Difference Reception.
- **CVS:** Brian Eason, VP, Consumer Health & Wellness.
- **Walgreens:** Robert Tompkins, Group VP.
- **Rite Aid:** Derrick Shaffer, Integrative Medicine Award 2020.
- **Wegmans:** Karen Shadders, Integrative Medicine Award 2019.
- **Racher Press:** Andrea Fallin, moderator of shopper panel.



Wegmans



RITE AID

Walgreens

♥ **CVS**Health®

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AAHP Integrative Medicine Award

Wegmans receives
AAHP award.

June 2019



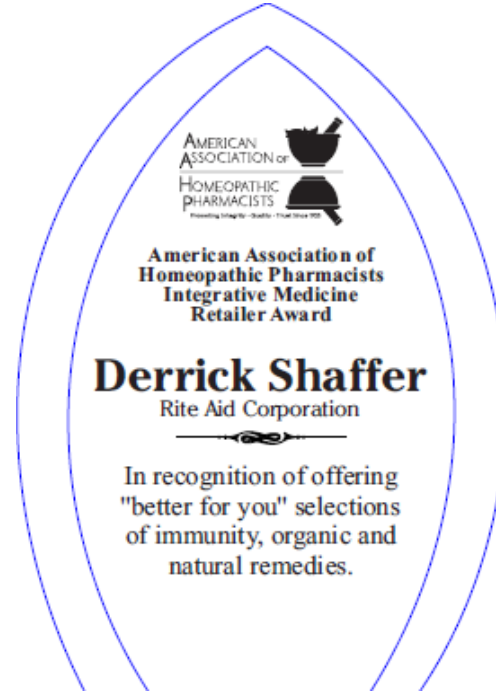
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AAHP Integrative Medicine Award

Congratulations this
year's honoree

Derrick Shaffer,
Category Manager,
Rite Aid Corporation



AAHP Survey Report / Panel Discussion

Survey of 600
homeopathic consumers
to help manufacturers.

Increased awareness
among retailers.

July 2020



AAHP Webinar

Homeopathic
Pharmacopoeia
Updates 2018–2019

Hosted by
Eric Foxman, RPh,
AAHP Secretary
June 2020



AAHP Education Goals 2021

- FDA Speaker Series
- Four Webinars Annually
- One In-person Education Event Annually



AAHP Members



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HOMECCARE

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New AAHP Members!



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Free Member Lanyards

Request for
future in-person events
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Member Plaque

Display at
events booths
& office lobby;
picture on website

Info@AAHP.Info

