Global Retailer and Manufacturer Alliance

ANSI Supplement Standardization

May 2019
Commitment to Quality

Goals were set by GRMA membership to create an architecture for success

• Single audit scheme developed as an unimpeachable industry standard for OTC’s, Dietary Supplements, and Cosmetics

• Public Standard and accompanying audit(s) would be a living document encompassing all regulatory requirements, cGMP guidelines and industry best practices

• Eliminate redundant audits and related issues

• Create consistency with auditor qualification, training and calibration
Creation of Standard

Stakeholder Solution was to Create an ANSI Public Standard

- Engage with NSF - recognized standards development organization
- Consensus driven process in a representative joint committee format involving Industry Stakeholders (manufacturers and retailers), Public Health Representative, and Users
- Due Process – required transparency, public comments and appeals

Dietary Supplements – Awarded Designation NFS/ANSI Standard 455-2

- Publication of DS Standard in December 2018 → 36 months in the making
- OTC Drug (NSF/ANSI 455-4) and Cosmetic (NSF/ANSI 455-3) published
- ReposiTrak / GRMAuditsphere architecture built for management of audit process and results
- Initial auditor training completed on scheme and process, ongoing auditor training/capacity building continues
## Public vs. Private Standards

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<thead>
<tr>
<th>Public (ANSI Standards)</th>
<th>Private Standards</th>
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<tr>
<td>Consumer Trust because they are public – not created or developed by special interest or private group</td>
<td>Consumers don’t know what criteria are used to create them</td>
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<td>ANSI Standards are recognized by industry and regulators alike - requirement</td>
<td>May not hold up to scrutiny of state or federal regulators / regulations</td>
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<td>Third Party Certifiers (CB’s) must certify to ANSI Standards</td>
<td>Certification Bodies may not be able to certify to a private standard</td>
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## Benefits to all Stakeholders

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<th>Retailers</th>
<th>Manufacturers</th>
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<tr>
<td>Employ single audit standard across category with objective grade</td>
<td>Single audit visit to address entire class of trade – and beyond</td>
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<td>Reduced regulatory burden – confidence in results and ongoing integrity</td>
<td>Focus quality on products and improvements – not the next audit</td>
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<td>Transparency into audit results and metadata</td>
<td>Metadata – a gold mine of information and constant analysis for fairness</td>
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<td>Sourcing and bid process simplified – know who makes the cut beforehand</td>
<td>Eliminate operational interruptions</td>
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<td>Ultimately easier enforcement of quality standards of brands in their stores</td>
<td>Opportunities through ResposiTrak / GRMAuditsphere contact base</td>
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<td>Rising Tide...</td>
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What’s Next?

- Key retailers have mandated the GRMA audit scheme for OTC Drugs and Cosmetics for this year and beyond
- Dietary Supplements next on horizon....
- Expansion of Scope into areas of GRMA's community (i.e. medical devices, international sourcing)
- Membership Programs Set – www.GRMAlliance.org/membership
- Retailers will require GMP audits to 455 for all imported items
- CB’s, Consultants, and other Stakeholders can learn about 455 through training

GRMA Annual Summit - 2019

- August 5-7
- Chicago Sheraton O'Hare – Easy travel accommodations
- Retailer 455 expectations panel
- Medical Devices/Consumer Products update
- CBD discussion panel
- Consumer Goods Forum speaker
- Social and Ethical Standard Development Panel
- Expansion of the 455 reach (Warehousing, etc.)
THANK YOU!
For more information on how to become a member - visit us at: www.GRMAAlliance.org

Follow us on social media @GRMAAlliance