USP: Advancing Public Health through Quality Standards

ANSI World Standards Week
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Markus Lipp, Ph.D.
Mission: To improve the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

What we do:

- Develop and provide standards that define the authenticity, identity, purity or impurity of food, drugs and dietary supplements, thus helping to ensure product integrity and the safety of consumers and brands.
  - Since 1820, nonprofit, private, independent, and self-funded
  - Headquartered in Rockville, MD; 600+ employees; facilities in India, China, Switzerland, Brazil
  - Expert volunteers are scientific decision-makers.
Quality standards defining the authenticity, identity and purity, thus the integrity of

- Drugs (*United States Pharmacopeia* and the *National Formulary*)
- Food ingredients (*Food Chemicals Codex*)
- Dietary supplements (*Dietary Supplement Compendium*)

Promoting the Quality of Medicines (PQM), a dedicated anti-counterfeit program aiding developing countries focusing on

- Capacity building
- Education
- Technical Support and Leadership
Core Compendial Programs

- The *United States Pharmacopeia* and the *National Formulary* (USP–NF)
- *Food Chemicals Codex*
- *USP Dietary Supplements Compendium*
- Reference Standards
- Standards for quality criteria (authenticity, identity, purity), test methods for their verification and reference materials from one source.
Contaminated Glycerin
Glycerin and DEG (>800 reported deaths)

1937 USA – Sulfanilamide elixir, 107 deaths
Implementation of the FD&C Act in 1938
1969 South Africa – Sedative, 7 deaths
1985 Austria – DEG in wine
1986 India – Medicinal glycerin, 14 deaths
1990 Nigeria – Acetaminophen syrup for children, 40 deaths
1990/92 Bangladesh – Acetaminophen syrup for children, 339 deaths
1995/96 Haiti – Cough medicine, 85 deaths
2006 Panama - Cough and anti-allergy syrup, 116 deaths
2007 Panama –Toothpaste
2008-09 Nigeria –Baby Teething Mixture, 50 deaths
also findings in toothpaste on US market
Occurrence:
Toothpaste and drugs

Problem:
Pharma cGMP did not require testing for impurities

Solution:
FDA tasked USP to modify standards, DEG testing became mandatory under pharma cGMP

Glycerine (Glycerol)
Edible and GRAS

- Light colored
- Slightly viscous liquid at room temp.
- Sweet taste

Diethylene Glycol
(“Antifreeze”) POISON!
Contaminated Heparin
Drugs: Contaminated Heparin (2008)

Reference: FDA website
Problem: economically motivated adulteration

Heparin: approved drug (blood thinner)

OSCS: adulterant, unknown pharmacological activity, toxic (anaphylactic shock), behaves *in-vitro* like heparin

Solution:
Update of heparin standard ID tests using $^{1}H$ NMR, HPLC

Additional Reference Standards:
- USP Heparin Sodium Identification RS
- USP Heparin Sodium System Suitability RS
Combating substandard and counterfeit drugs in developing countries: HIV/AIDS, malaria, tuberculosis
PQM Program Objectives

Build capacity & strengthen QA systems
- Train and educate in quality assurance
- Establish postmarketing surveillance programs

Help increase supply of QA medicines
- Improve manufacturers’ GMP compliance
- Test procurement agency samples (UNICEF)

Combat availability of counterfeit meds
- Provide technical assistance to IMPACT, INTERPOL and other initiatives
- Raise awareness w/PSAs, campaigns

Provide technical leadership
- Advocate globally for medicine quality
- Promote new detection technologies
PQM Countries

Africa
- Benin, Ethiopia, Ghana, Kenya, Liberia, Mali, Rwanda, Senegal, Tanzania, Uganda

Asia
- Cambodia, India, Indonesia, Laos, Myanmar/Burma, Nepal, Philippines, Thailand, Vietnam, Yunnan Province of China

Latin America and Caribbean
- Bolivia, Brazil, Colombia, Ecuador, Guyana, Guatemala, Jamaica, Panama, Paraguay, Peru, Suriname

Europe/Eurasia
- Russia
PQM Successes in an Ongoing Struggle

- **Sub-Saharan Africa**
  - One third of antimalarial medicines sampled in three African nations found to be substandard in large-scale USP-WHO study
  - Medicine vendors in major Dakar illicit market banished as result of PQM-supported communications campaign in Senegal
  - Network of African medicine quality control laboratories (NAMCOL) founded

- **Southeast Asia**
  - Nearly 65% of illegal pharmacies in Cambodia closed by government in five-month period with assistance from USAID-PQM, WHO
  - Philippines national drug quality lab achieved ISO accreditation with PQM support

- **Latin America and the Caribbean**
  - Peru national drug quality lab achieved ISO accreditation with PQM support

- **Europe and Eurasia**
  - PQM trained 98 Roszdravnadzor analysts in 8 customized lab courses
Thank You