U.S. FDA/EMA REGULATORY INSPECTION AND ENFORCEMENT TRENDS

by Lynne Byers and Jenny Yu

Like the pharmaceutical industry, the insurance industry must review regulatory trends in order to understand them. NSF provides expert GMP advice, on demand, to insurance company Munich Re when it is assessing the risk of insuring a client.

The FDA Shutdown and Import Bans graph (Figure 1) is based on 10 years of publicly declared enforced and voluntary facility shutdowns. Munich Re performed an in-depth review of U.S. FDA 483s issued to drug manufacturers between 2009 and 2017. To complement this work and to compare it with the EMA's findings, an assessment was also made of the publicly available data from EMA regulatory authorities using the EudraGMDP database of non-conformance reports. As the information provided in EudraGMDP is a summary of findings, it is not possible to perform the assessment in the same way as the U.S. FDA data. However, both sets of data provide a good insight into the findings from these agencies.

The data provide the following insights:

> Both the FDA and EMA have the highest number of import bans/non-conformance reports from sites in China and India (*Figures 1 and 2*).

> Emerging trends from FDA drug inspections (*Figure 3*) affect:

- Procedures, both availability and use in QC, production, cleaning, maintenance and process controls (essentially the lack of a Pharmaceutical Quality System)
- Lack of scientifically sound test methods
- Inadequate investigations
- Cleaning and sanitation
- Training

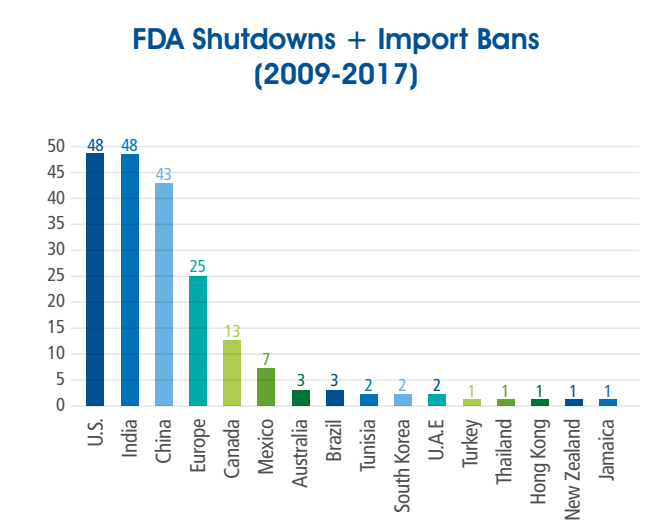


Figure 1

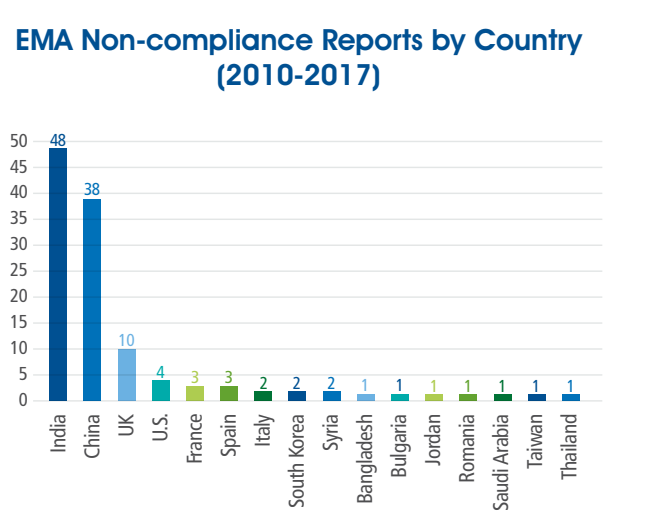


Figure 2

> Emerging trends from EMA inspections (*Figure 4*) affect:

- Pharmaceutical Quality System
- Production
- Documentation
- QC
- Premises and equipment

The findings from both regulators are unexpectedly very similar.

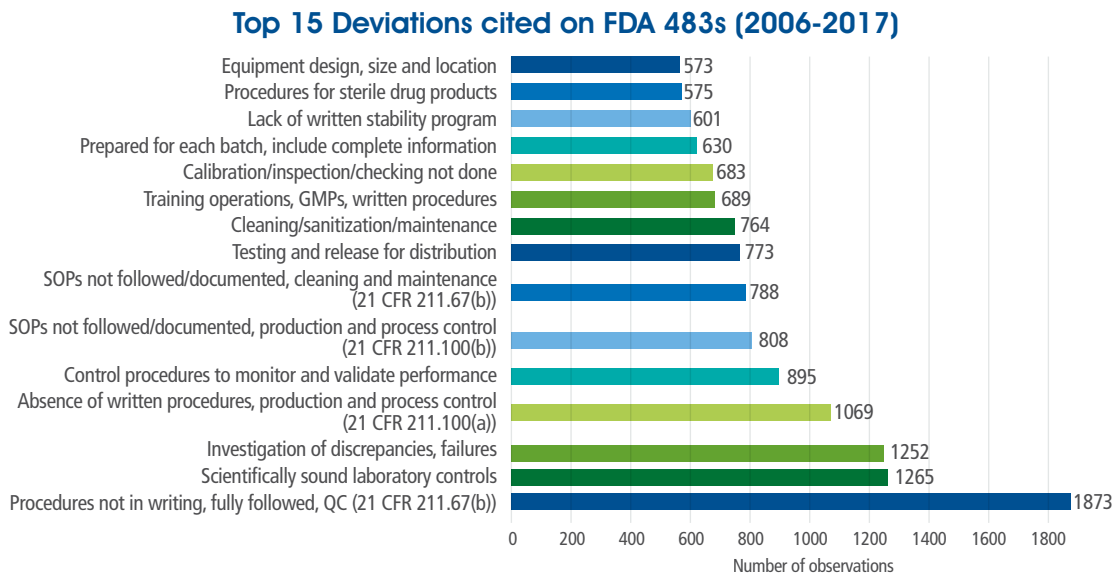


Figure 3

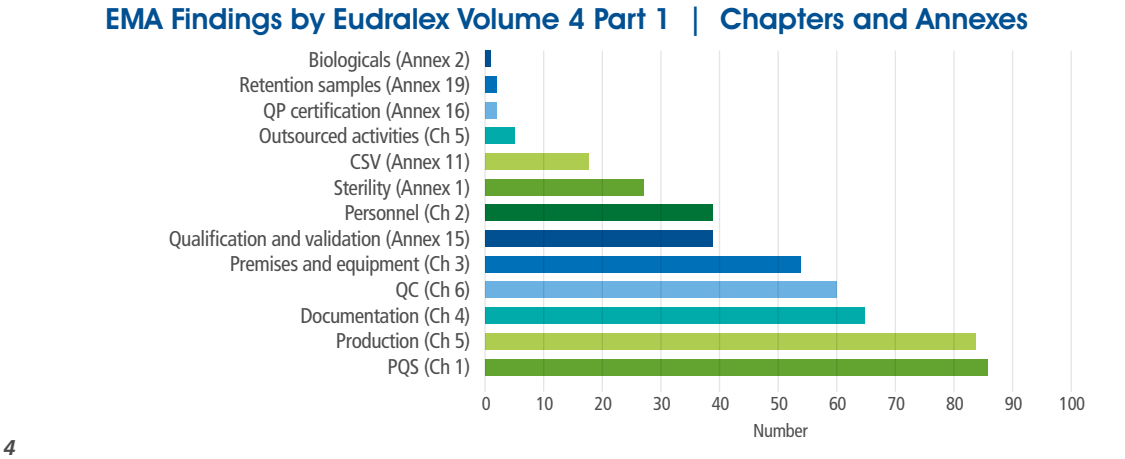


Figure 4

Questions managers need to ask themselves:

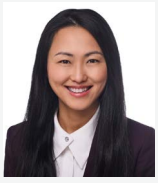
- Do we have clear procedures for all necessary activities, which are easily understandable and followed by all staff?
- Do we have sufficient numbers of staff to perform activities and operate under control?
- What evidence do I have to support my assessment that my site is under control?
- Are staff sufficiently trained and educated in the activities they perform?
- Do we understand what is required to operate in compliance with data integrity requirements?
- Is my environmental monitoring program linked to my contamination control strategy?
- Do we have plans in place to meet the proposed Annex 1 of EudraLex Volume 4?
- Are the cleaning methods used still appropriate?
- After reading this article and reviewing the data, WHAT ACTION DO I NEED TO TAKE?

View our related learning resources – **www.nsf.org/info/pblibrary**:

- Video: **Introduction to Pharma Data Integrity eLearning**
- Webinar: **How to Write a Contamination Control Strategy for Your Facility**

ABOUT THE AUTHORS

Lynne Byers has gained more than 35 years' of extensive pharmaceutical manufacturing management and QA experience working for three major international pharmaceutical manufacturers, culminating in the role of Global Head (VP) of External Supply Operations QA for Novartis in Switzerland. In addition, she worked as Head of Inspectorate and Licensing for the MHRA from 2004-2006. She joined NSF in 2017.



Jenny Yu leads the Life Science Risk Solutions team at Munich Re Group (www.munichre.com/landingpages/corporate/en/equip.html), focusing on providing new risk solutions and bespoke solutions specifically designed for the life science industry. Jenny and her team have developed a first-in-class insurance solution to address regulatory non-compliance risks and supply chain risks under the brand "EQuIP" for pharma, biotech and medical device companies. Jenny also leads multi-line/multi-year integrated programs for life science companies within Munich Re.

For more information, contact **healthsciences@nsf.org** or visit **www.nsfhealthsciences.org**

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