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
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.
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

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