BDMA(I) PRESENTATION

GLOBAL REGULATORS CONCLAVE

International Regulatory Convergence to Promote Accessibility and Affordability of Quality Medicines

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ABOUT BDMA(I)

The Bulk Drug Manufacturers Association (India) (BDMA(I)) was formed in the year 1991 as an all India representative body of the bulk drug industry, with its Head Quarters in Hyderabad, Telangana State, India.

Association works as an interface between the Industry & Governments both at Central and State level and represents on all common issue effecting the API industry with sole objective of achieving Growth of this sector.

Association also encourage and assist mutual help and co-operation among the Member units. Association works closely with Government Bodies for Framing & executing legislative measures with any state or central government or any such authorities on any matter directly or indirectly effecting the industry effecting the industry, trade and commerce relating to Bulk Drug Industry. The objectives of the Association are also to encourage & formulate methods for developing indigenous as well as export market for Bulk Drugs manufactured in India.

ABOUT BDMA(I)

- Member companies includes Global companies such as DRL, Aurobindo,Lupin, Cipla, MSN, Hetero, Laurus & Few others.

- There are about 350 member companies of which about 75% are MSME companies.

Members Experience with Different Countries/ Regions :

1.Our members are supplying API's Globally in about 200 countries and have been dealing with Regulatory in different regions / Countries.

Members Experience with Different Countries/ Regions :

2. There are two types of system prevailing Globally. In one system prevailing in US, EU , TGA The manufacturer is required to directly deal with Regulatory and in another system such as prevailing in Japan, Korea , Taiwan & China , the manufacturer is required to deal through in country care taker mostly a distributor company.

Members Experience with Different Countries/ Regions :

3. Both system have its own merits & demerits. However based on Members experience, We can say that system permitting manufacturer to deal directly is more convenient and brings better compliance.

Members Experience with Different Countries/ Regions :

4. Members are also experiencing very high registration costs of 75-100 K USD & prolonged registration time in certain countries Industry expects some kind of rationale in registration Costs & approval time lines.

Members Experience with Different Countries/ Regions :

5. It is understood Chinese Regulatory expects best of specs from USP/EP/JP/CP monographs. Additionally they expect API manufacturer to not use recovered solvents even after equivalence is demonstrated.

Industry expects science based regulations.

Expectations from International regulators & Procurement Agencies

1. Presently Monographs differ across geographies. Is it possible to have common ground on Methods of Analysis & specifications? This would avoid multiple validations and duplication of work for manufacturers.

Expectations from International regulators & Procurement Agencies

2. Definitions of Major and Minor changes are vague & loosely worded giving room for discretion for reviewer. If the Definitions are clearly worded, the manufacturer will also have greater understanding of regulatory process involved in incorporating changes.

Expectations from International regulators & Procurement Agencies

3. Regulatory audits combined with customer audits keeps the manufacturer busy. An Mid size company has to face an average of 75-80 audits per year leaving manufacturer QA little time to focus on operations. We do not see the need for customer audits for a defined time period after a regulator has completed the audit mandates.

Is it possible to avoid multiplicity of audits?

Expectations from International regulators & Procurement Agencies

4. It would greatly ease the burden of compliance on manufacturer if the regulatory agencies can have Mutual Recognition pact thereby avoiding multiple regulatory audits for same product in same facility.

Expectations from International regulators & Procurement Agencies

5. There is need for common ground on sampling and Analysis of input materials. While some permits Statistical sampling methods such as $\sqrt{n+1}$, Some others insist on every container to be analyzed.

Expectations from International regulators & Procurement Agencies

6. For exports to EU , an additional document of Written confirmation is required for Indian manufacturers. Industry is of the opinion that API Business is B to B with adequate testing/ evaluation facilities on both sides. This is duplication of already existing documentation of WHO-GMP and can be revisited at least for API manufacturers.

Expectations from International regulators & Procurement Agencies

7. Whenever any alert is issued by any of the PIC/S country against any manufacturer, their exports to all PIC/S countries come to stop. However when the Alert is lifted, the country initiating the Alert does not circulate the information & alert continues with other countries.

CONCLUSION

THANK YOU