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Quality Issue with Indian Pharmaceuticals Industry

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Abstract

United States Food & Drug Administration (US-FDA) barred three facilities of Ranbaxy Laboratories from supplying medicines to the world's largest pharmaceutical market. Other Indian companies like Wockhardt, RPG life sciences, Strides Arcolab, Fresenius Kabi AG; west Bengal have also been barred from exporting to USA.

India accounts for nearly 40% of Generic Drugs & OTC (over the counter) products & 10% of Finished Dosages used in US market. India is the biggest exporter of medicines to US. Almost, 200 manufacturing facilities in India are US-FDA approved which include Multi National Companies. Pharma exports from India grew 10.55% year on year to $ 14.6 billion during 2012-13, according to Pharmaceutical Export Promotion Council.

Indian Pharmaceutical Industry cannot ignore the huge Export Market, earning in foreign currency, reputation, only due to ONE MAJOR factor,i.e. QUALITY ! The entire industry must rise up to the expectations & beyond, to re-earn the reputation, respect, reliability, in the world market.

Disturbance **2**

The disturbing trend is evident in the numbers. Data shows:

Year	No. of companies	% to approved facilities in India
2011	**7**	**3.5 %**
2012	**2**	**1.0 %**
2013	**19**	**9.5 %**

The exports to US market from Indian Pharma Industry is $ 4.23 Billion amounting to 29**%** of total Pharma Exports of $ 14.6 Billion during the year 2012-13.

Key Words:

ISO International Standards Organisation
GMP Good Manufacturing Practices
TQM Total Quality Management
SQC Statistical Quality Control
SOP Standard Operating Procedure
US FDA United States - Food Drugs Administration

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Defining Quality:

When the expression "Quality" is used, we think of excellent product or service that fulfills or exceeds our expectations. These expectations are based on intended use and selling price. When product surpasses our expectations we consider that Quality. It is our perception.

A more definitive definition of Quality is given in ISO 9000:2000. **It is defined as the degree to which a set of inherent characteristics fulfills requirements.** Degree means that Quality can be used with adjectives such as Poor, Good, Excellent etc. Inherent is defined as existing in product/service as a permanent characteristic. Characteristics can be Quantitative or Qualitative. Requirement is a need or expectation that is stated: generally implied by organization, its customers,& other interested parties or could be obligatory.

Quality has different dimensions. However for Pharma company,important and related dimensions could be :

(1) Performance: Primary Product Characteristics
(2) Conformance: Meeting specifications or industry standards.
(3) Reliability : Consistency of performance
(4) Service: Resolution of problems & complaints. 3
(5) Reputation: Past performance & other intangibles.

Practices in Pharma Industry for Quality Assurance:

- GMP (Good Manufacturing Practice) is observed throughout the manufacturing facility, right from vendor approval, testing of materials, till finished goods are formed. It includes internal external environment cleanliness, testing methods, various validations, documentations etc.
- Approved Suppliers: Suppliers that meet an organization's selection criteria & have been added to the approved list. The approved process include submission of samples for testing, Quality conformation, inspection of supplier's manufacturing facility & supplier's quality system.
- Certification from supplier: Organization may create Quality standards that, when achieved, become the basis for supplier to be certified.
- Standards: These include minimum level of Quality, specifications for conformation, method of Quality Inspection etc.
- Certification: ISO, GMP, TQM. Indian pharma companies prefer suppliers with ISO &GMP certification.
- Acceptance/ Rejection report: History should be available with organization as well as it's suppliers & should be reviewed, along with traceable records.

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- Measuring devices: A check should be made to ensure that measuring device calibration dates have not expired.
- Workers: Indicators of worker capability to look for might include the number of hours of statistical Quality control (SQC) or Total Quality Management (TQM) traning, worker certification held & use of process control chart by the equipment operators.
- Machines: Process control chart is a way to monitor machine capability. Maintenance history, frequency of breakdowns & preventive maintenance activity need to be observed. Validation of each &every machine is a must.
- Process Control: If organization has a program of Statistical control (SQC) or statistical process controls (SPC), it should be reviewed.
- Documentations systems/procedures – All instructions, Standard operating procedure (SOP) & inspection procedures should be in writing. Training program with periodic updates should be in place.
- **Periodic Audits: The audit should take place periodically either conducted by Corporate QUALITY ASSURANCE team or special Audit Team**.
- **Continuous Improvement: Organization** needs to practice KAIZEN/TQM for continuous improvement rather than becoming complacent in the existing situation.

Lapses in Indian Pharma Industry observed by US-FDA:

- Suspected contamination.
- Embedded hair.
- Oil spots on tablets
- Lack of hot and cold water in toilets.
- Inadequate written instructions to employees for proper Quality checks.
- Torn files found in a waste heap & urinals that emptied into an open drain in a bathroom six meters from the entrance to a sterile manufacturing area.
- Unlabeled vials in the glass-ware washing area.
- Unlabeled test tubes
- Unlabeled batches of drugs

Cost of "non conformance" of Quality paid by Indian PharmaIndutry.

1 Ranbaxy agreed to pay a fine of $ 500 million (Rs 3000 crs approx.) for violation of Good Mfg. Processes

2 Ranbaxy recalled certain dosages of Generic Atorvastatin after US-FDA suspected it contained glass particles.

3 Exports to US market is banned for almost of 19 Indian companies.

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4 Indian companies which command a major share of this market will certainly be subject to tight scrutiny.

5 India is aggressively planning to achieve exports target of $ 25 Billion in 2014-15 from $14.6 Billion in 2012-13, almost a huge jump of $10 Billion ,which will get hampered.

Remedial Measures:

Basically, it is a major problem of MINDSET& CULTURE which Indian companies need to change. Self introspection required.

- Robust system in place in the organization throughout.
- Corporate management should own the responsibility.
- Adequate corrective measures in terms of infrastructure, documentation or in terms of attitude and behavior.
- Invest more in compliance system.
- Regular audit by audit team.
- Training to existing as well as new employees.
- Not to by-pass or take casual approach towards various processes & procedures leading to systematic lapses.
- Continuous Improvement.

Conclusion:

In short, Indian Pharma Industry should think of Quality issues in totality & not in isolation. Industry is at Maturity level and needs to think beyond US-FDA requirements & should rise up as an Example Of Excellence before the world.

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