ISA Delhi Section

Setting the Standard for Automation™

Automation in Pharma and cGMP Environment

Ramesh Walia

ISA-D: “Fertilizer, Food and Pharma Automation Meet (FFP) 2019"

Contents

- Brief Overview of Pharmaceutical Industry
- Key Requirements of Pharma industry
- Key Challenges
- Automation Requirements of Pharma industry
- Typical System Architecture
- Focus On Key Parameters

Brief Overview of Pharmaceutical Industry

- Industry growing at enormous rate
- World's total Market is USD 1.2 Trillion
- India is world's largest producer of Generic Pharmaceuticals
- India having 30% share in Generic Pharmaceuticals in USA.
- Exports from India Approx USD 19.7 Billion
- Domestic Consumption is also rising due to
  - Growing awareness on healthcare
  - Increase in spending power
  - Health Insurance schemes
  - Penetration of healthcare facilities to remote corners
- Lots of Talent available at competitive cost
- Focus on R&D and Clinical research leading to cost efficiency

Key Requirements of Pharma industry

- Patient Safety
- Product Quality
- Data Integrity

Shares of [redacted] slipped 19 per cent after reports said the US Food and Drug Administration (USFDA) flagged lack of good manufacturing practices.

[redacted] Adulterated drugs

[redacted] Pharma tanks on USFDA observations

Drug major [redacted] said it has received a warning letter …..in a regulatory filing.

"Excelling at quality and compliance is one of our top priorities."

Drug firm [redacted] Pharmaceuticals said it has got approval from the ….

[redacted] signs consent decree. $500 million penalty

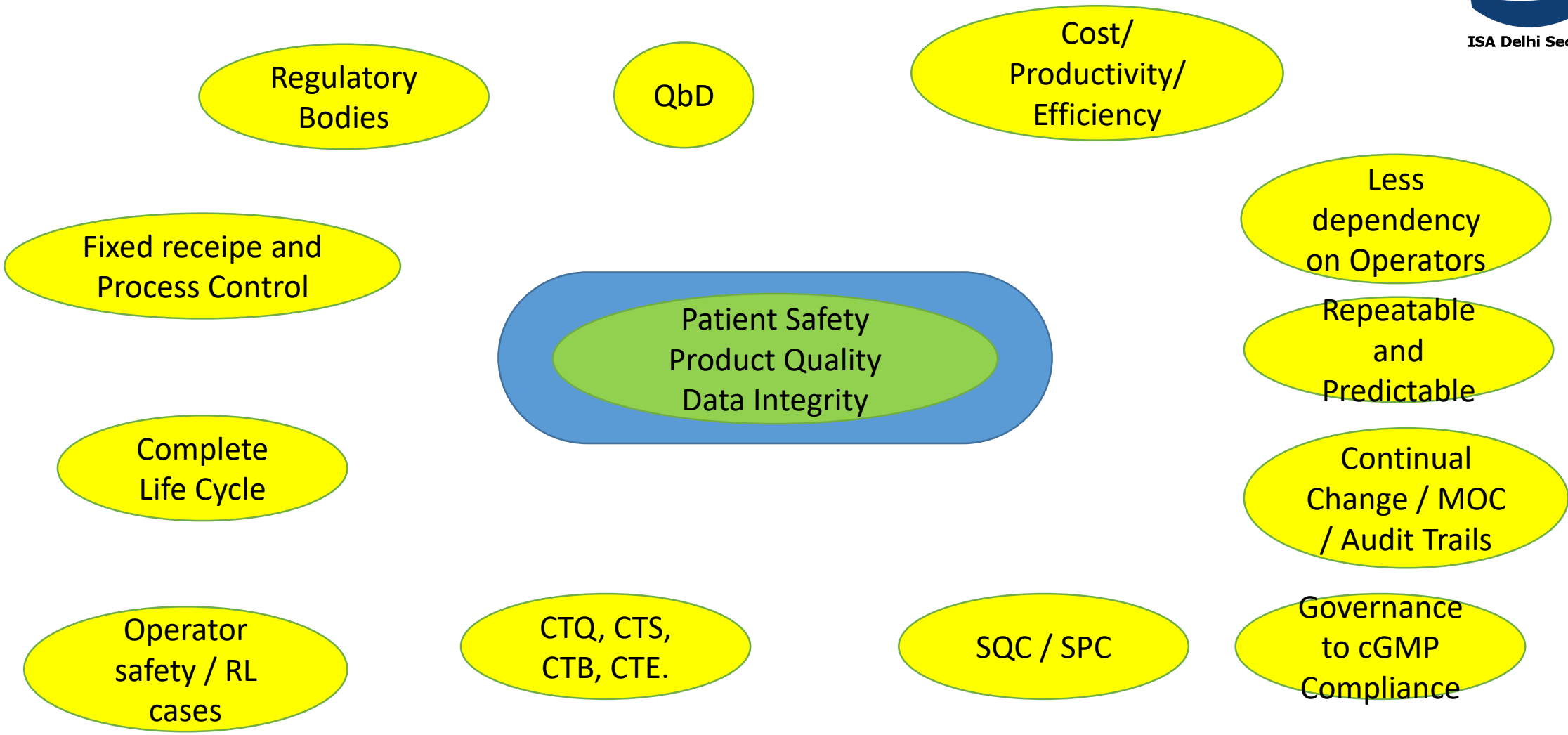
Key Challenges

- Strict evaluation by local and International Regulatory Agencies like USFDA , TGA, CDSCO
- Data Integrity
  - Manual records
  - Falsification of data.
  - Non-Compliance to procedures
  - Cuttings / alterations
- Operations are manual (people dependent)
- Batch to batch variations in quality or yield
- Inefficient processes, Non Repeatable and Non predictable results
- Rejections
- Lack of connectivity of ERP / MES
- Lack of statistical control

Key Challenges

- Cost Control (Competition)
- Use of safe technologies
- Continuous Change in technology.
- Thousands of SKUs

Automation Requirements of Pharma industry



Automation Requirements of Pharma industry

ISA Delhi Section

- Compliance to various Regulatory Requirements
- Validation / Qualification of the system
- GAMP
- No contamination of product due to manual handling
- Care for environment
- Batch tracking
- Security of Data (History, Alarms , Events)
- Repeatable process , Predictable quality
- Consistency of operations, yield and product quality.
- 21 CFR Part 11 Compliance
- Management of Change / Audit Trails
- No human errors

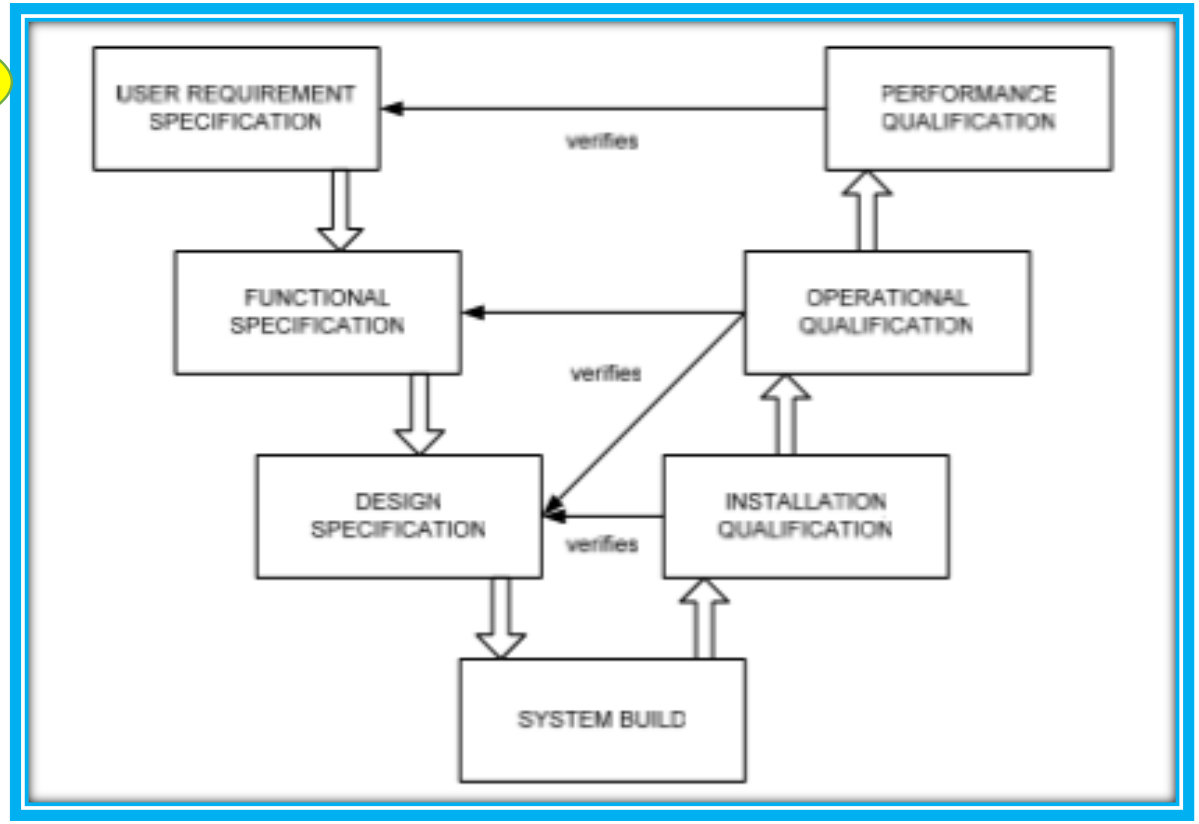
Automation Requirements of Pharma industry

ISA Delhi Section

- Complex technology and Lengthy processes.
- New technological developments happening quickly
- Heavily dependent upon R&D.
- Handling of Hazaradous chemicals / drugs
- Impact of drugs on operators
- High Capex → Multiple product plants
- Warehousing

Typical Implementation Model

Are my Requirements clear?



Is my system producing right quality of Product?

Is the system problem built?

QUATITATIVE RISK ASSESSMENT (QRA)

ISA Delhi Section

Risk = Severity * Probability * Detectability

- Know the Risk
- Quantify its severity / Consequence
- Estimate its probability of Occurrence
- How soon can we detect the risk?
- Mitigation:
  - Eliminate by Design
  - Reduce to an acceptable level
  - Verify
- Calculate the residual risk (after mitigation)
- Document and communicate at every level.

Patient safety,
Product quality
Data Integrity
&
Safety

What is the smell of LPG gas?

Higher the Risk --→ Higher is the mitigation
Special Focus on Critical Parameters
Failure Mode Effect Analysis

KOPs / Critical Parameters

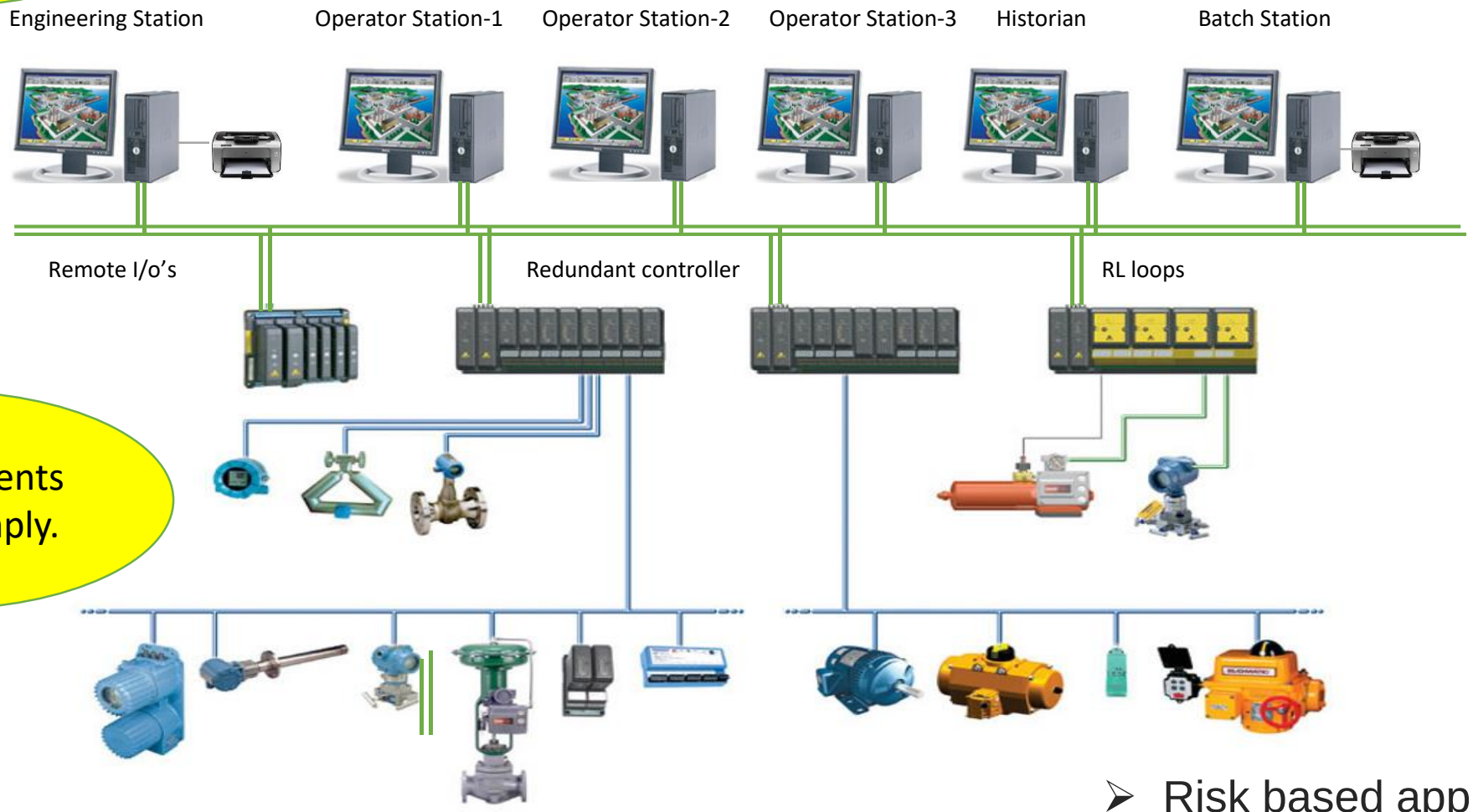
After how much time will I detect the risk?

		Probability			
		< 1x per 4 year (W1)	= 1x per 3 year (W2)	= 1x per 2 year (W3)	> 1x per year (W4)
Potential Consequence	(1)	1	2	3	4
	(2)	2	4	6	8
	(3)	3	6	9	12
	(4)	4*	8	12	16

Connection to ERP, Warehouse auotmation

ISA Delhi Section

Typical System Architecture In Pharmaceutical Environment



All components should comply.

- Global Clock across the site.

- Risk based approach
- Entire Life Cycle of the system
- Data retention

FOR BUSINESS CONTINUITY

AUTOMATION
IS NOT
“NICE TO HAVE”

IT IS
“MUST HAVE”

ISA Delhi Section

THANKS

rameshwalia@gmail.com