BiOZEEN™

We are into the business of Saving Lives

Risk Based Equipment Qualification based on ICH Q9

Devak Padmanabhan

30 Aug 2023

Agenda

- Networking Details
- BiOZEEN range of Solutions
- Biopharmaceutical Landscape for (Developmental) Countries
- Quality Control System
- Quality Risk Management
- Risk Assessment – Equipment, based on ICH Q9
- Q&A

Networking Details

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https://www.facebook.com/profile.php?id=100004414549305&mibextid=ZbWKwL

Value Added Integration Services

Automation

Training

Design & Build

Bioprocess Engineering

Regulatory & Validation Services

COMPLETE
BIOPROCESS
ENGINEERING
SOLUTIONS

BiOZEEN

BiOZEEN - Bangalore Biotech Labs Pvt. Ltd.

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Hennur – Bagalur Road,

Bengaluru 560077

BiOZEEN Process Technology AG

Heissackerweg 29

4513 Langendorf

TÜV NORD
TÜV NORD CERT GmbH
ISO 9001

Biopharmaceutical Landscape for (Developmental) Countries

Head Quarters: Bangalore

Employees: 300 +

Number of Business Lines: 6

Number of Product Lines: 8

- Empowered 800+ professionals to serve the industry better
- Engineered designs which improved yield up to 6 times
- Delivered solutions which are 65% energy efficient
- Rendering services to 21 countries
- Served 53 customer across borders
- Approved vendor and partner to global companies
- CE certified process systems, TUV certified equipments
- ASME U-stamped Facilities
- PIGMP certified GMP compliant Biopilot Laboratory for Microbiological & Physiological Testing
- ISO 9001:2015 certified

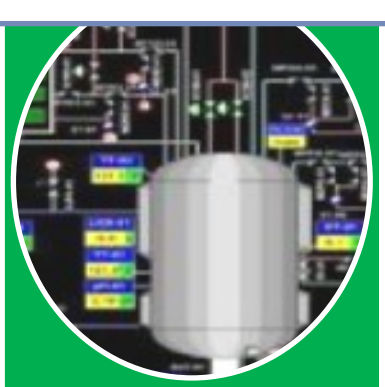
PEP BUSINESS MODEL

BiOZEEN

PROCESS, EQUIPMENT, PEOPLE

Design Build Solutions

- Bioreactor systems
- Fermentor systems
- Process Vessels
- Inline Buffer Dilution Systems
- Continuous Lysis Systems
- CIP and SIP systems
- Filtration systems
- Bio-Kill systems
- Sanitary Vessels
- Crystallizers
- Interconnection piping



Automation Solutions

- Plant Automation
- PLC Programming
- DCS Systems
- Automation Upgradation

Technology Services

- Process Optimization & Scaleup
- Contamination troubleshooting

Research & Development

- Efficiency Improvement studies
- Glycosylation
- Perfusion with micro-carriers
- Algae culture
- High cell density of VERO / CHO cell lines

Manpower Training

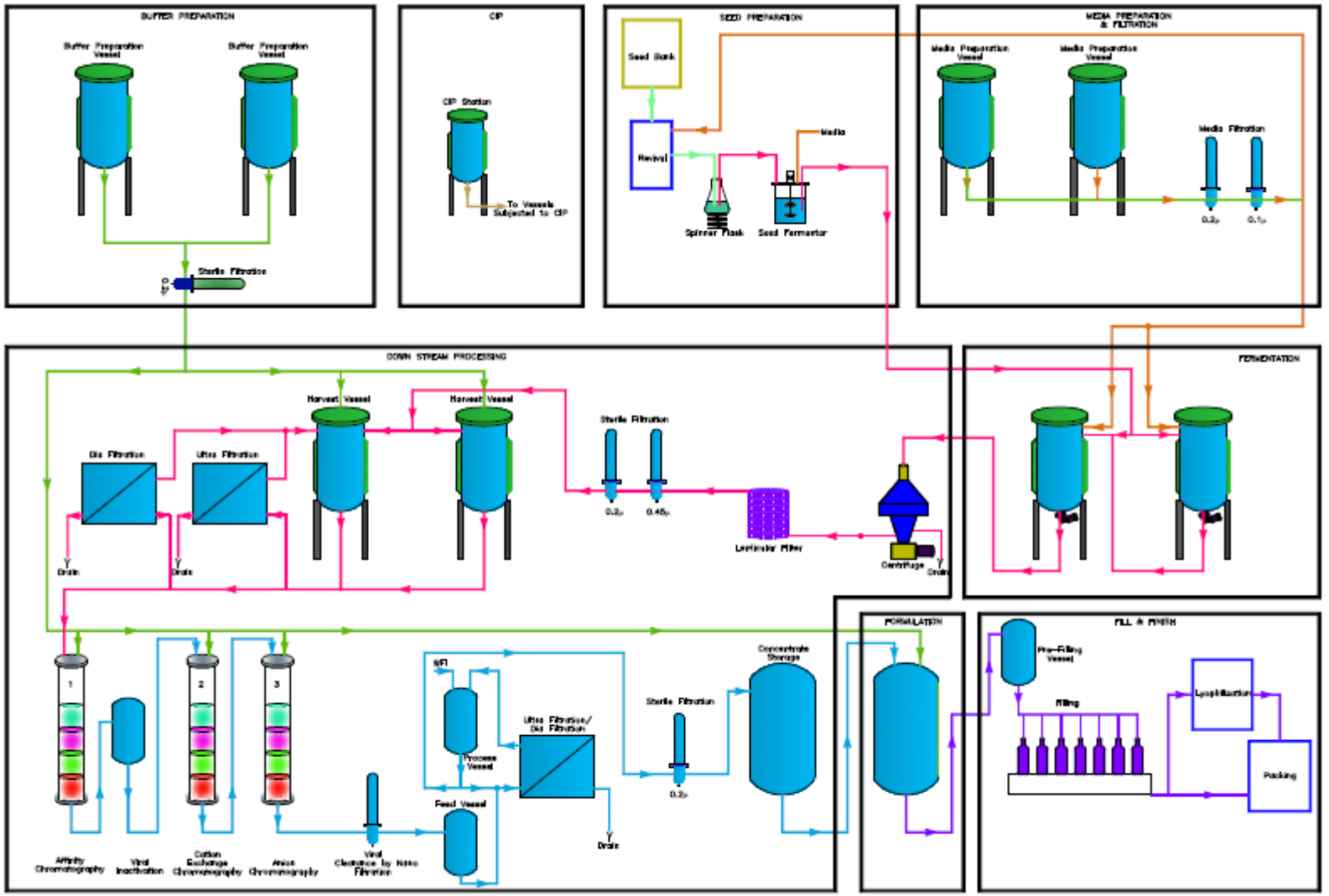
- Fermentation Technology
- Mammalian Cell Culture Technology
- Downstream Processing
- Sterilization & Filtration Technology
- Bioprocess Engineering
- Regulatory Aspects & Documentation

BiOZEEN Regulatory Services

- Filter Train Optimization Study
- Compatibility Study
- Product based Integrity Study
- Bacterial Retention Study
- Protein & Preservative Binding Study

Portfolio of BiOZEEN

A representative process flow diagram



LEGEND:—

BiOZEEN Scope of Supply

Virtual Tour

Portfolio of BiOZEEN

Integrates comprehensive domain knowledge & extensive expertise to engineer solutions with unmatched capabilities

Compliance to International Guidelines

- ASME BPE 2022 for Vessel and Piping Manufacturing.
  ASME Section VIII, Div. 1 for Pressure Vessel Manufacturing.
- US FDA 21 CFR Part 11 for Electronic Records and Electronic Signatures
- GAMP for Validation of Automated System
  GAMP 5 for A Risk-Based Approach to Compliant GxP Computerized Systems
- IEC 60529 Standards for protection of panel enclosure.
- EN/IEC-60204 and UL 608 for electrical work
- ICH Q9 for Quality Risk Management
  WHO Guidelines for Good Manufacturing Practice

Your Single Source Solution

Product Portfolio

- Media, Buffer & Process Tanks, Super Skids
- Fermentors & Bioreactors
- Clean – In – Place Systems (CIP)
- Steam– In – Place Systems (SIP)
- Crystallizers & Bio Kill Systems
- MF, UF and Viral Clearance Skids
- Inline Dilution System

QUALITY CONTROL SYSTEM

QUALITY CONTROL SYSTEM

BiOZEEN

Quality System Manual

QMS: ISO 9001:2015

ISO 9001:2015

CONTACT DETAILS:-

Vibin B Joseph

Executive Director

Bangalore Biotech Labs Pvt. Ltd (BiOZEEN)

Bangalore

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ISSUED TO: QMS Lead

Approved by: Vibin B Joseph

BiOZEEN

Quality System Manual

(Unit-2)

QMS: ISO 9001:2015

ISO 9001:2015

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Approved by: Vibin B Joseph

QUALITY CONTROL SYSTEM

Sl. No	Document Title	Start Page	End Page	Revision
I)	Cover Page	1	1	R00
II)	Content Sheet: DOC. No.: BBL/CORP-QSM/D/01	1	6	R00
III)	SECTION -1,2,3: DOC. No.: BBL/CORP-QSM/D/02	7	14	R08
	• Company Profile (Introduction)	1	4	R08
	• Infrastructure	5	5	R08
	• Human Resource	6	7	R08
	• Organization Chart	8	8	R08
	• Scope of Certification & Out of Scope	9	10	R08
	• Reference Standards	10	10	R08
	• Revision record	11	12	R08
	• List of Abbreviations Used	13	13	R08
	• Distribution List / Copy Holder	14	14	R08
IV)	SECTION - 4: Context of the Organization - Quality Management System requirements: DOC. No.: BBL/CORP-QSM/D/04	1	14	R08
	Quality Management System Requirements	1	2	R08
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	4.2 - Needs and Expectations of the interested parties	6	6	R08
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V)	SECTION - 5: LEADERSHIP: DOC. No.: BBL/CORP-QSM/D/05	1	19	R08
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VI)	SECTION - 6: Planning: DOC. No: BBL/CORP-QSM/D/06	1	4	R06
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VII)	SECTION - 7: Support: DOC. No.: BBL/CORP-QSM/D/08	1	45	R05
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QUALITY CONTROL SYSTEM

Risk It to Get the Biscuit:

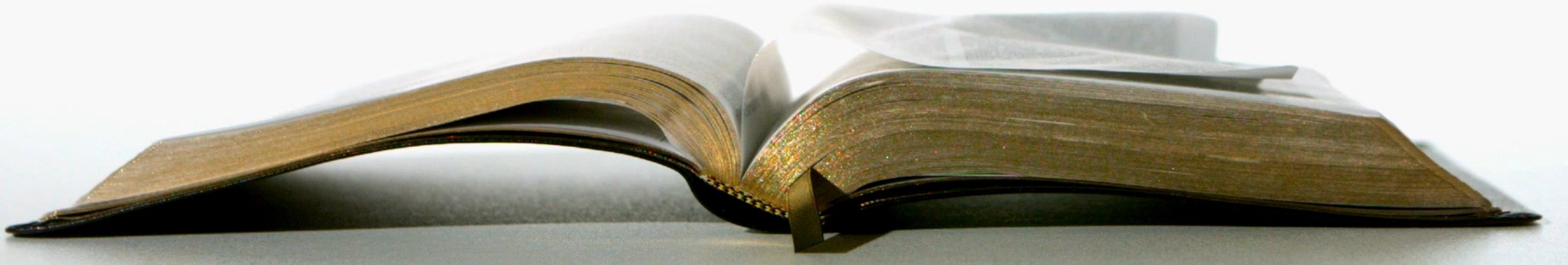
Quality Risk Management - BiOZEEN

Quality Risk Management - BiOZEEN

What is Quality Risk Management?

Quality Risk Management is a systematic process for assessing, controlling, and reviewing risks that could potentially impact an organization's products, services, or operations. It involves identifying potential risks, analyzing their likelihood and impact, and implementing strategies to mitigate or eliminate them.

In today's rapidly changing business environment, organizations face a multitude of risks, including financial, operational, reputational, and regulatory risks. Quality Risk Management provides a structured approach for managing these risks, ensuring that they are identified and addressed before they have a negative impact on the organization.



The Process of Quality Risk Management

The process of Quality Risk Management involves four main steps: identification, assessment, control, and review.

1) *Identification* is the first step, where potential risks are identified and documented. This can be done through brainstorming sessions, reviewing historical data, or using other methods to identify potential risks.

2) *Assessment* is the second step, where the identified risks are evaluated based on their likelihood and impact. This step helps prioritize risks for further action.

Quality Risk Management - BiOZEEN

3) *Control* is the third step, where strategies are developed to mitigate or eliminate the identified risks. This can include implementing controls, changing processes, or other actions to reduce the likelihood or impact of the risk.

4) *Review* is the final step, where the effectiveness of the risk management process is evaluated and any necessary changes are made to improve future risk management efforts.

Risk Assessment Techniques

Risk Assessment is a critical component of Quality Risk Management. There are several techniques that can be used to identify and assess risks, including Failure Mode and Effects Analysis (**FMEA**), Hazard Analysis and Critical Control Points (**HACCP**), and Process Hazard Analysis (**PHA**).

FMEA is commonly used in the automotive and aerospace industries to identify potential failure modes and their effects on a system or process.

HACCP is frequently used in the food industry to identify and control hazards that could cause foodborne illness. ‘

PHA is often used in the chemical and pharmaceutical industries to identify potential hazards associated with the use of chemicals and other hazardous materials.

RISK ASSESSMENT - BiOZEEN

The Risk Assessment follows 3 steps:

- The Hazard Identification: Identify the hazards and determine its impact.

- The Risk Analysis: Estimate the risk level by linking (qualitatively or quantitatively) likelihood of occurrence and severity of harms. (probability of detection can be factored)

- The Risk Evaluation: Compares the identified and analyzed risk against a predefined risk criteria. Considers the strength of evidence for the 3 fundamental questions.

Q1: What might go wrong?

Q2: What is the likelihood (probability) it will go wrong?

Q3: What are the consequences (severity)?

THE RISK ANALYSIS (ICH Q9, clause 4.3)

- There could be many different meanings of risk, depending on the type of risk management program.
- In general, "probability" and "severity" will be quantified.
- In a given program, the *definitions* will fine-tune the concepts so that a risk management program can be created and applied.
- Accept the different "realities" among the stakeholders.
- Harmonized guidance needs to focus the concepts into useful terms for the purpose (e.g. protection of employee/operator [Q9])

THE RISK EVALUATION (ICH Q9, clause 4.3)

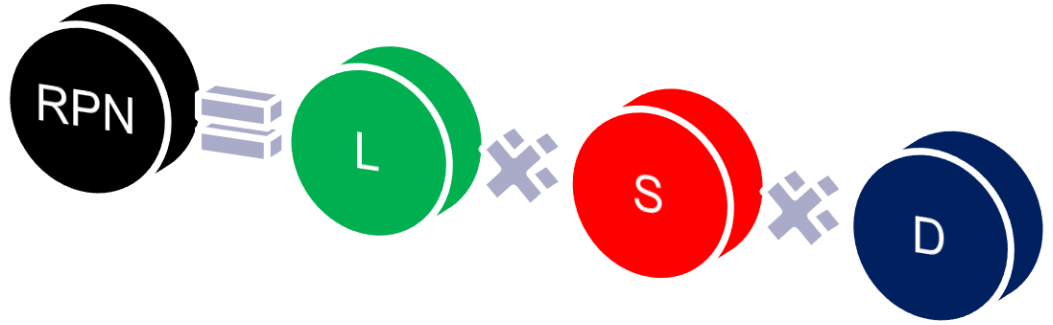
a) Assess Likelihood (probability / frequency) or **Probability of Failure (L)**

b) Assess the **Severity of Impact (S)**

c) Probability of **Detection (D)**

d) Risk Priority Number (RPN): Quantitative Estimation

e) Overall Priority (OP): Qualitative Estimation (High, Medium, Low)



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Probability of Failure (L)	Possible failure rates	Ranking
Very High: Adverse event occurs during every alternate transaction or more	≥ 1 in 2	5
Medium: Generally associated with adverse event that occurs occasionally.	1 in 400	3
Remote: Failure is unlikely, no failure ever associated with tested system control.	1 in 15,00,000	1

Seriousness of Effects (S)	Possible Impact	Ranking
Hazardous (without warning)	System / Software will completely disturb and/or noncompliance with government regulation, calculation report failure condition occurred.	5
Medium	Due to this type of adverse events, post processes are affected, and minor corrections may be required.	3
None or Minor	No Effect Or Adverse event occurs during execution of non GMP transaction.	1

RISK ASSESSMENT - BiOZEEN

Probability of Detection (D)	Possible Detection Control(s)	Ranking
Almost impossible	User will not detect, and no known control(s) is available	5
Medium	User will detect fault mode while executing the post process transaction of current stage of operation / process.	3
Almost High	Spreadsheet will not allow user to execute immediately next transaction process.	1

Overall Priority (OP)	Overall Priority Calculation Result
Low	< 25
Medium	25 to 75
High	> 75

RISK ASSESSMENT - BiOZEEN

5.1 RISKS RELATED TO VESSELS MANUFACTURING

Serial No.	Risk Area	Risk Impact	(L)	(S)	(D)	RPN (L*S*D)	(OP)	Measures/Mitigation	(L)	(S)	(D)	RPN (L*S*D)	(OP)	Carrying Risk (Y/N)	Opportunity for Improvement after Mitigation (Y/N)	Responsibility
1.	Shortage of vessel fitters/Manual welders	Vessels manufacturing may not complete on Time & Delay in Delivery	1	5	1	5	L	• Overtime will be given to complete the activities. • Outsourcing Vessel manufacturing for Non ASME Vessels • Employing new fitters/welders • Hiring new fitters/welders on contract basis	1	3	1	3	L	N	Y	• Incharge-Production • Incharge-Factory
2.	Experienced fitters to be deputed to unplanned site activities		3	5	1	15	L	• Outsourcing fit up/welding at site to third party. • Fitters can be deputed to site & Outsourcing /Overtime will be given to complete the activities in house	1	3	1	3	L	Y	Y	• Incharge-Production • Incharge-Factory
3.	TIG Manual Welding machines breakdown		1	5	1	5	L	• Sending Machine for repair • Preventive maintenance as per schedule • Overtime will be given to complete the activities. • Outsourcing welding to Biofab engineering • Hiring only machines on rental basis • Keep 2nos machines in stock. • Train the engineer in house for maintenance (Opportunity)	1	3	1	3	L	Y	Y	• Incharge-Production • Incharge-Factory • Incharge-Maintenance • Incharge-Purchase
4.	Welding torches leaking/not working		1	5	1	5	L	• Preventive maintenance as per schedule • Min 2nos torches are available as spares in stock	1	1	1	1	L	Y	N	• Incharge-Production • Incharge-Maintenance
5.	Required Spares are not available in stock Ex: panel board, Motor		3	5	3	45	M	• Critical spares as per supplier recommendations are kept in stock	1	3	1	3	L	Y	N	• Incharge-Production

RISK ASSESSMENT - BiOZEEN

5.2 RISKS RELATED TO PIPING MANUFACTURING

Serial No.	Risk Area	Risk Impact	(L)	(S)	(D)	RPN (L*S*D)	(OP)	Measures/Mitigation	(L)	(S)	(D)	RPN (L*S*D)	(OP)	Carrying Risk (Y/N)	Opportunity for Improvement after Mitigation (Y/N)	Responsibility
27.	Shortage of Piping fitters	Piping manufacturing may not complete on Time & Delay in Delivery	1	5	1	5	L	• Overtime will be given to complete the activities. • Employing new fitters • Training to existing fitters • Hiring new fitters/welders on contract basis	1	3	1	3	L	Y	Y	• Incharge-Production • Incharge-Factory
28.	Experienced fitters/welders to be deputed to unplanned site activities		3	5	1	15	L	• Outsourcing fit up/welding at site to third party. • Sending fitter/welders to site based on criticality and resource planning locally.	1	3	1	3	L	Y	Y	• Incharge-Production • Incharge-Factory
29.	Pipe cutting machine breakdown		3	5	1	15	L	• Outsourcing or hire on rental pipe cutting machine. • 3 nos kept in stock	1	3	1	3	L	Y	N	• Incharge-Production • Incharge-Factory
30.	Pipe bending machine breakdown		3	5	1	15	L	• Outsourcing to pipe bending suppliers	1	3	1	3	L	Y	N	• Incharge-Production • Incharge-Purchase
31.	Delay in machining components		3	5	3	45	M	• Stock of standard connectors • Alternate vendors for machining • Alternate vendor for readymade connectors • Sharing weekly priority list to supplier	1	5	1	5	L	Y	Y	• Incharge-Production • Incharge- Purchase
32.	Instruments are not available for production		1	5	1	5	L	• Standard instruments are in stock -2 set. • Borescope machine on renal basis (outsourcing) • New instruments requirement reviewed for each drawing	1	3	1	3	L	N	N	• Incharge-Production • Incharge-QC

QUALITY RISK MANAGEMENT – CASE STUDIES

QRM – CASE STUDIES

Quality Risk Management Process for a Bioreactor:

1) Risks related to the utility supply and interconnection with other process systems.
2) Risks related to sterility / contamination.
3) Risks related to process to be handled.
4) Risks related to damage or malfunctioning of equipment.
5) Risks related to abnormal use by authorized operator.
6) Risks related to unauthorized / unidentified user.
7) Operator HAZOP.

QRM – CASE STUDIES

5.1 RISKS RELATED TO THE UTILITY SUPPLY AND INTERCONNECTION WITH OTHER PROCESS SYSTEMS

Sl.No	Risk Scenario	Impact	Before Mitigation				Measures/ Mitigation	After Mitigation			
			L	S	D	O.P=L×S×D		L	S	D	O.P=L×S×D
1.	Utility not available	Equipment Malfunctioning and Process Failure	3	3	1	L	a. Utility lines designed with suitable regulating valves, sensors & interlocks/alarms are provided. b. Customer should ensure that the availability of utilities are qualified and uniform (*)	1	3	1	L
2.	Pure Steam Pressure (High and Low)	High Pressure: a. If steam pressure exceeds the operating value [equipment's rupture disk burst pressure] - potential damage of equipment, failure of components & instruments. b. Potential personnel injury. c. Potential environmental impact - Heat generation within the room, suite significant with the reversible effects.	1	3	1	L	a. Pressure sensor is provided before pure steam pressure regulating valve. Diaphragm Pressure Gauge in the pure steam header line in combined skid - P & ID is provided for visual check. b. PRV is manually set to maintain 2 bar (g) to regulate the head pressure. c. A Rupture Disk with burst indicator is also installed on the vessel lid. d. Periodic inspection & maintenance of the PRV and utility (*)	1	3	1	L
3.		Low Pressure: If less, desired process temperature will not be attained, resulting in SIP failure.	3	3	1	L	a. Low pressure detection is possible with the help of pressure sensor and diaphragm pressure gauge. b. In any potential situation of vacuum, the process air inlet valve is activated to maintain atmospheric pressure. c. Periodic inspection & maintenance of the PRV and utility (*)	1	3	1	L

QRM – CASE STUDIES

5.2 RISKS RELATED TO STERILITY / CONTAMINATION

Sl.No	Risk Scenario	Impact	Before Mitigation				Measures/ Mitigation	After Mitigation			
			L	S	D	O.P=L×S×D		L	S	D	O.P=L×S×D
1.	Filter Integrity fails	Contamination and Product loss.	1	5	1	L	Integrity connectors are provided and at every batch (pre and post), filter integrity test to be performed (*)	1	5	1	L
2.	Contamination of system/culture media	Product quality is affected. (Improper sterilization, improper handling)	3	5	1	L	a. Fully automated SIP sequences for empty / full vessel sterilization, independent addition ports sterilization, inlet & exhaust filter sterilization, media filtration SIP and sampling valve sterilization is provided. b. Temperature sensor has been provided before the steam trap for applicable SIP able lines. c. pH & DO calibr d. ation are also provided through the transmitter's operation. e. High & Low value alarms are provided and it can be viewed on the IPC. f. Operator training, handling, Preventive maintenance (*)	1	5	1	L
3.	Filter fitting	Product loss	1	5	1	L	Integrity ports are provided and at every batch filter integrity test to be performed (*)	1	5	1	L
4.	Leakage of gaskets/O-rings	a. Pressure loss, b. spillage, c. sterility failure d. operator safety is compromised etc.	1	5	1	L	a. Pressure Hold test sequence is provided to check for damages/improper assembly. b. Periodic check and maintenance to detect the leakages (*)	1	5	1	L

QRM – CASE STUDIES

5.3 RISKS RELATED TO PROCESS TO BE HANDLED

Sl.No	Risk Scenario	Impact	Before Mitigation				Measures/ Mitigation	After Mitigation			
			L	S	D	O.P=L×S×D		L	S	D	O.P=L×S×D
1.	Improper agitation process	a. Improper mixing/heat transfer/MOTR. (temp, gas dispersion) b. Product quality will be affected (yield, potency, plan/schedule)	1	5	1	L	a. Vessel is provided with Bottom Driven Agitator to ensure homogenous mixing and agitation is controlled by variable frequency drive. b. Feedback sensor is provided for measuring actual RPM. c. Drive diagnostics are considered.	1	5	1	L
2.	Improper Temperature during Mixing process (high and low)	a. Improper temperature reading of the Vessel temperature sensor. b. Product quality will be affected (yield, potency, plan/schedule) c. Improper sterilization	1	5	1	L	a. Alarms & Interlocks considered for the temperature sensor & it can be viewed on the HMI/SCADA screen. b. Jacket temperature sensor can be monitored for comparison. c. Periodic calibration of temperature sensors (*)	1	5	1	L
3.	Media Loss during FSIP/Fermentation	a. Reduction of harvest broth.	3	1	3	L	a. Condenser in vent line to prevent media loss. b. High temperature interlocks and alarms provided. c. Periodic monitoring of steam traps (*)	1	1	1	L
4.	When suite environmental conditions exceed the specified limit	Installed instruments & equipment may function erratically giving inconsistent readings and process may get affected	1	5	3	L	a. Selected instruments that are installed in the equipment have wide range of operating conditions. b. HVAC is periodically monitored (*)	1	5	3	L

QRM – CASE STUDIES

5.4 RISKS RELATED TO DAMAGE OR MALFUNCTIONING OF EQUIPMENT

Sl.No	Risk Scenario	Impact	Before Mitigation				Measures/ Mitigation	After Mitigation			
			L	S	D	O.P=L×S×D		L	S	D	O.P=L×S×D
1.	Loss of integrity within the sterile boundary	Pressure loss, spillage, sterility failure, operator safety is compromised.	1	5	1	L	a. Pressure Hold test sequence is provided to check for damages/improper assembly. b. Customer to ensure periodic check and maintenance to detect the leakages of diaphragms, O-rings & connectors (*)	1	5	1	L
2.	Short Circuit / Circuit Break	Electrical/electronic components fail	1	5	1	L	MCBs, Circuit MPCB's, Surge protectors and fuses inside the TB are provided in the Main Control Panel. When tripped, alarm will be logged in the alarm history and can be viewed on HMI screen.	1	5	1	L
3.	Field Instruments removed or wire disconnected	Malfunctioning of process, erratic readings	1	5	1	L	Wire Break Alarms are provided and alarms will be logged in the alarm history and can be viewed on IPC screen.	1	5	1	L
4.	Dust and Water entry in the control cabinet	a. All control cabinet components get damaged. b. Short circuit	1	5	1	L	a. IP 54 protection standalone cabinet is provided. b. Fan filters with louvers is provided. c. Periodic maintenance (*)	1	5	1	L
5.	Dust & Water/Liquid spillage in the electrical assembly of Agitator	The motor's electrical assembly gets damaged.	1	5	1	L	a. SS Cover for Agitator's Electrical Assembly & Motor is provided. b. Periodic maintenance (*)	1	5	1	L

QRM – CASE STUDIES

5.5 RISKS RELATED TO ABNORMAL USE BY AUTHORIZED OPERATOR

Sl.No	Risk Scenario	Impact	Before Mitigation				Measures/ Mitigation	After Mitigation			
			L	S	D	O.P=L×S×D		L	S	D	O.P=L×S×D
1.	Improper shut down of system	License will get corrupted	3	3	1	L	a. Log-out buttons provided in HMI/SCADA. b. Recommended to run the system under UPS (*)	1	3	1	L
2.	Wrong parameter entries	Batch Failure depending on which parameter is entered incorrectly.	1	5	5	M	a. The change of parameters is permitted only within a certain range by access control. b. System does not accept values outside the range. c. Change to the parameters/settings are logged in the Audit Trail. d. Audit trail must be reviewed periodically by Authorized personnel.	1	5	1	L
3.	Enable / Disable of Alarms	Abnormal situation will go undetected	1	5	5	M	a. The change of alarm settings is permitted only within a certain range by access control. b. Enable or Disable alarms will be captured in audit trail.	1	5	1	L
4.	Change of report saving/logging time	All sequence steps will not be logged.	1	5	3	L	a. The change of logging time for reports is permitted only within a certain range by access control. b. Change of report saving/ Logging time will be captured in audit trail.	1	5	1	L
5.	Abort of sequence during operation	a. Incomplete batch sequence b. Product quality is affected c. Increase in downtime of production plan	1	5	1	L	a. 3 second timer for continuous pressing of hold button. b. Pop-up confirmation for Yes / No is additionally provided.	1	5	1	L

QRM – CASE STUDIES

5.6 RISKS RELATED TO UNAUTHORIZED / UNIDENTIFIED USER

Sl.No	Risk Scenario	Impact	Before Mitigation				Measures/ Mitigation	After Mitigation			
			L	S	D	O.P=L×S×D		L	S	D	O.P=L×S×D
1.	Access (Physical/Software) by non-qualified, untrained or unidentified personnel to equipment	Physical: Product loss	1	5	1	L	Access control to site and building to be secured by customer (*)	1	5	1	L
2.		Software: Product loss, Data breach, Virus infection, Software corruption if SCADA/HMI is not handled correctly	1	5	1	L	a. Firewall protection to access the software b. Access control for using the system is allowed only with correct entry of user name and correct password. c. Recommended updated Antivirus to be installed in Server and IPC (*)	1	5	1	L
3.	Unauthorized personnel attempts to modify the SCADA program when unattended by authorized personnel	Software corruption if SCADA/HMI is not handled correctly	1	3	3	L	a. 4 Levels of access control are defined for each user and authorization rights are configured to restrict unauthorized changes. b. All changes done in the SCADA system by any user will be captured in the Audit Trail. c. Structured Audit Trail report is configured that can be filtered date/time wise comparing the 'Old Value' and 'New Value'. d. Unique and complex password for each user is set and awareness training is provided during SAT to restrict password sharing.	1	3	1	L

QRM – CASE STUDIES

5.7 OPERATOR HAZOP

Sl.No	Risk Scenario	Impact	Before Mitigation				Measures/ Mitigation	After Mitigation			
			L	S	D	O.P=L×S×D		L	S	D	O.P=L×S×D
1.	Rupture of gaskets, SRV seat, steam lines.	Release of steam & supplied fluid in facility.	1	5	1	L	a. Preventive Maintenance procedures to be implemented by customer (*) b. RD and SRV vents to a safe location within the facility (directed to the floor).	1	5	1	L
2.	Light glass/ Sight glass gasket rupture/leakage	a. Injury b. loss of product c. exposure to personnel	1	5	1	L	a. Proper installation procedures to be followed for mounting of glass. b. Pressure Hold Test is performed to check the leakage of pressure and thereby the mounting of the mechanical components like Light/Sight Glasses are ensured. c. Preventive Maintenance procedures to be implemented by customer (*)	1	5	1	L
3.	Flexible tubes of addition system rupture (peristaltic pump tubes and flexible hose)	a. Operator safety is b. compromised c. spillage within room	1	5	1	L	a. Peristaltic: Single use tubing is recommended (*) b. Others: Preventive Maintenance procedures to be implemented (*)	1	5	1	L
4.	Pneumatic tube damage	a. Leakage of air. b. Valves will not function.	1	5	1	L	Preventive Maintenance procedures to be implemented by customer (*)	1	5	1	L

QRM – CASE STUDIES

6- RISK ASSESSMENT SUMMARY REPORT

Sl. No	Risk Scenario	Total No. of Risks	Overall Priority		
			Low (L)	Medium (M)	High (H)
1.	Risks related to the Utility Supply and Interconnection with other Process Systems	39	34	5	0
2.	Risks related to Sterility/Contamination	16	14	2	0
3.	Risks related to Process to be handled	19	16	3	0
4.	Risks related to Damage or Malfunctioning of Equipment	5	5	0	0
5.	Risks related to Abnormal Use by Authorized Operator	5	3	2	0
6.	Risks related to Unauthorized / Unidentified user	4	4	0	0
7.	Operator HAZOP	6	6	0	0

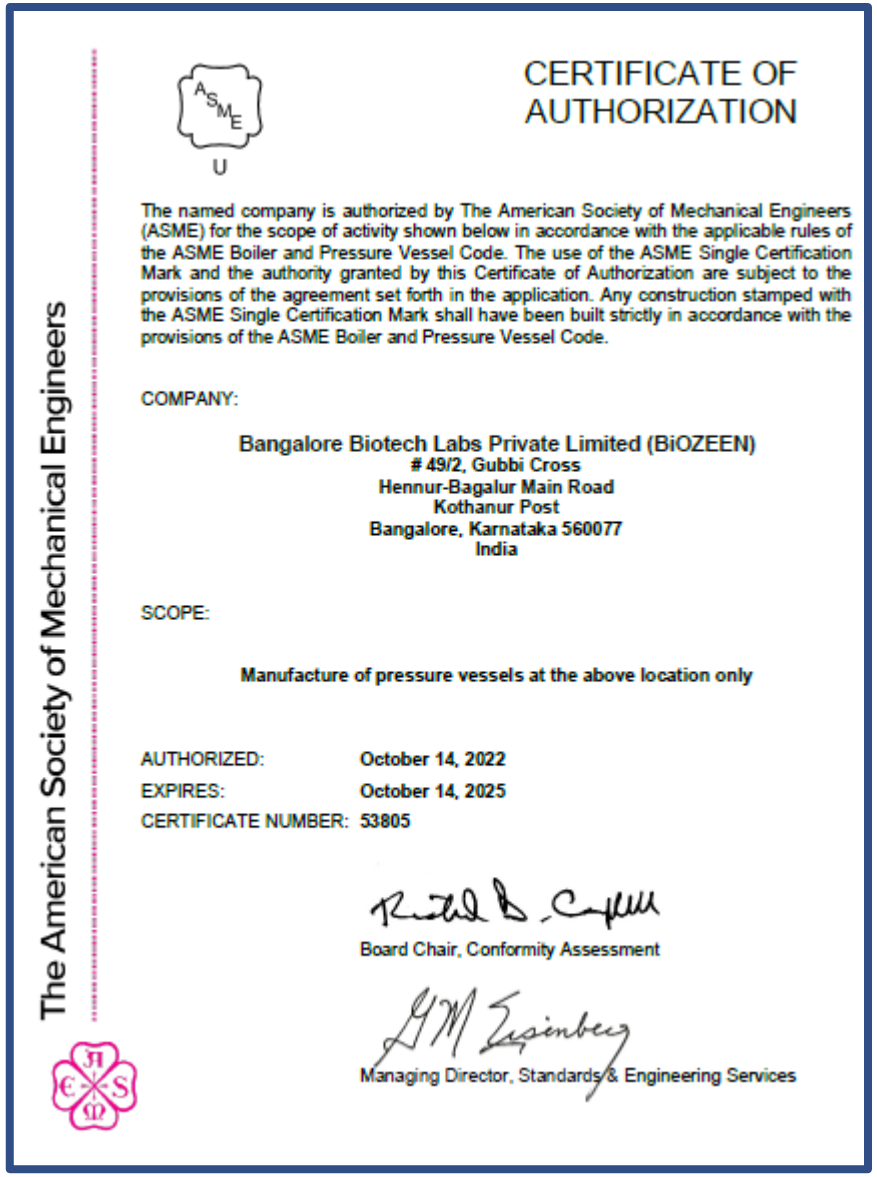
(*) not included in the scope of supply

ALTERNATE TOOLS FOR RISK ASSESSMENT METHODOLOGIES

Table A.3 – Applicability of techniques to the ISO 31000 process

Tools and techniques	Risk assessment process					Sub-clause
	Risk identification	Risk analysis			Risk evaluation	
		Consequence	Likelihood	Level of risk		
ALARP, ALARA and SFAIRP	NA	NA	NA	NA	SA	B.8.2
Bayesian analysis	NA	NA	SA	NA	NA	B.5.2
Bayesian networks	NA	NA	SA	NA	SA	B.5.3
Bow tie analysis	A	SA	A	A	A	B.4.2
Brainstorming	SA	A	NA	NA	NA	B.1.2
Business impact analysis	A	SA	NA	NA	NA	B.5.4
Causal mapping	A	A	NA	NA	NA	B.6.1
Cause-consequence analysis	A	SA	SA	A	A	B.5.5
Checklists, classifications and taxonomies	SA	NA	NA	NA	NA	B.2.2

ASME / ISO Authorization & Confirmation



The American Society of Mechanical Engineers

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CERTIFICATE OF AUTHORIZATION

The named company is authorized by The American Society of Mechanical Engineers (ASME) for the scope of activity shown below in accordance with the applicable rules of the ASME Boiler and Pressure Vessel Code. The use of the ASME Single Certification Mark and the authority granted by this Certificate of Authorization are subject to the provisions of the agreement set forth in the application. Any construction stamped with the ASME Single Certification Mark shall have been built strictly in accordance with the provisions of the ASME Boiler and Pressure Vessel Code.

COMPANY:

Bangalore Biotech Labs Private Limited (BiOZEEN)
 # 49/2, Gubbi Cross
Hennur-Bagalur Main Road
Kothanur Post
Bangalore, Karnataka 560077
India

SCOPE:

Manufacture of pressure vessels at the above location only

AUTHORIZED: **October 14, 2022**
EXPIRES: **October 14, 2025**
CERTIFICATE NUMBER: **53805**

Board Chair, Conformity Assessment

Managing Director, Standards & Engineering Services

TÜV NORD

CERTIFICATE

Management system as per
ISO 9001 : 2015

The Certification Body TÜV NORD CERT GmbH hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

BANGALORE BIOTECH LABS PVT. LTD. (BIOZEEN)
49/2, Gubbi Cross, Hennur-Bagalur road,
Kothanur Post, Bengaluru - 560 077,
Karnataka,
India
and other location as per annexure & sub-certificate

BiOZEEN

operates a management system in accordance with the requirements of ISO 9001:2015 and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope -

Design, Manufacture & Supply of Bioprocess Equipment and also Providing Training & Validation Services related to Bio Pharmaceutical Production.

Certificate Registration No.44 100 18391713
Audit Report No.2.5-4139/2008

Valid from 08.09.2021
Valid until 09.04.2024
Initial certification 10.04.2018

Certification Body
at TÜV NORD CERT GmbH

Mumbai, 08.09.2021

TÜV NORD CERT GmbH Langemarckstrasse 20 45141 Essen www.tuev-nord-cert.com

TUV India Pvt. Ltd., 801, Raheja Plaza – 1, L.B.S. Marg, Ghatkopar (W), Mumbai - 400 086, India www.tuvnord.com/in

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Book an Appointment

- Networking Details
- BiOZEEN range of Solutions
- Biopharmaceutical Landscape for (Developmental) Countries
- Quality Control System
- Quality Risk Management
- Risk Assessment – Equipment, based on ICH Q9
- Q&A

Thank You !

For any queries contact us at

www.biozeen.com

devak.mk@biozeen.com

Devak

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