BiOZEEN's approach towards **Pharma 4.0** and going **Paperless**

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22 OCT 2022

Process Technologies for Health & Well Being

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
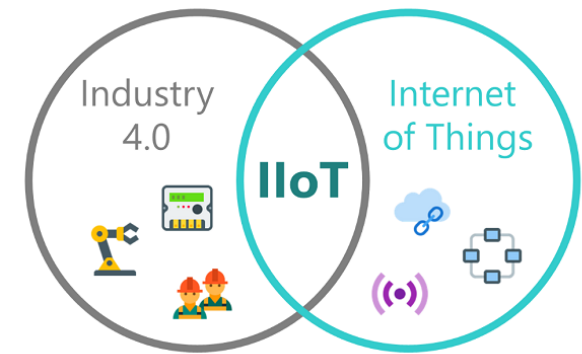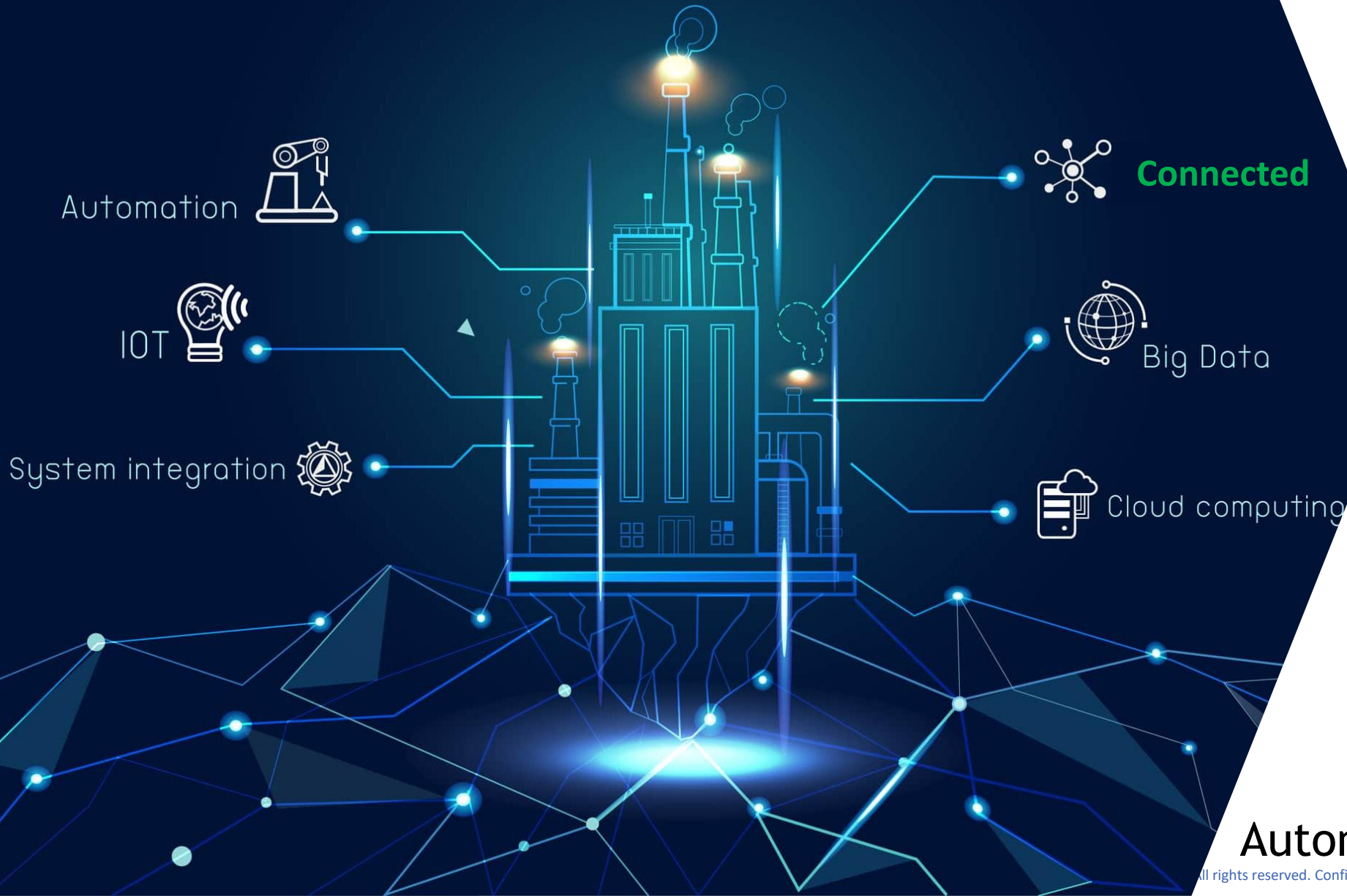- Regulatory Aspects & Documentation

BiOZEEN Regulatory Services

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

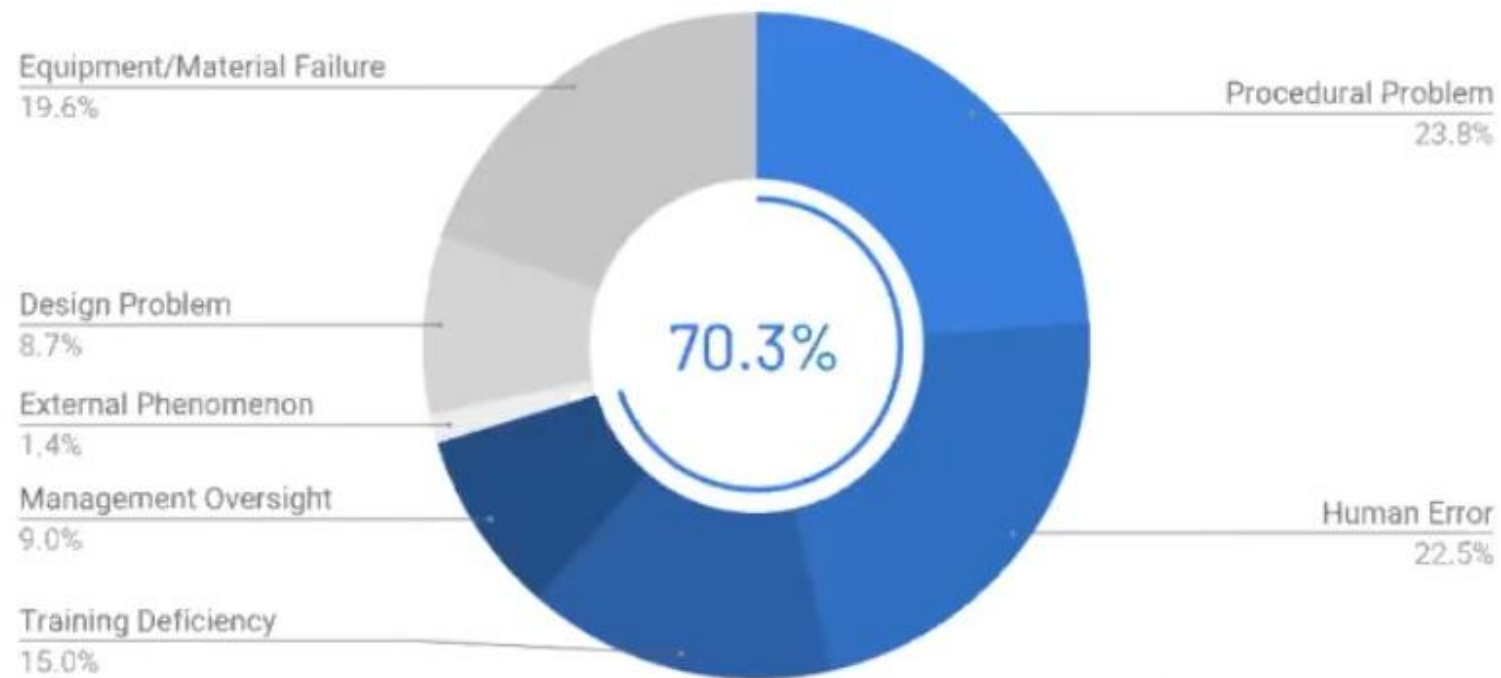Manufacturers spending $2T/year on automation, but **it's not solving their biggest problems**

Equipment/Material Failure
19.6%

Design Problem
8.7%

External Phenomenon
1.4%

Management Oversight
9.0%

Training Deficiency
15.0%

Procedural Problem
23.8%

Human Error
22.5%

70.3%

70-80% of factory failures are caused by **human-centric processes**

Source: IHS Markit, DOE "Human Performance Improvement Handbook"; Noria research

This is how **data analytics** is adding value
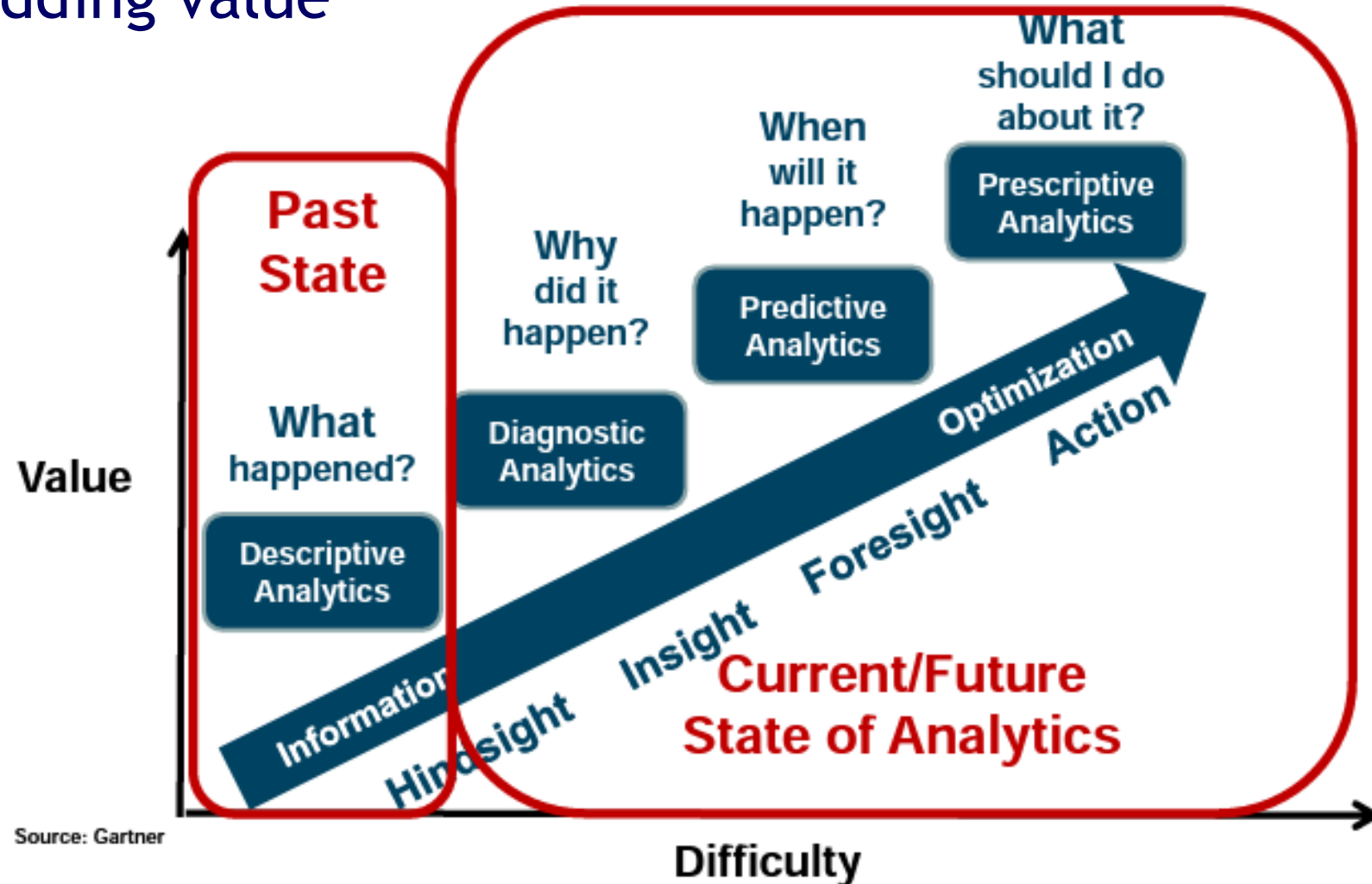
OEM Equipment Handshake
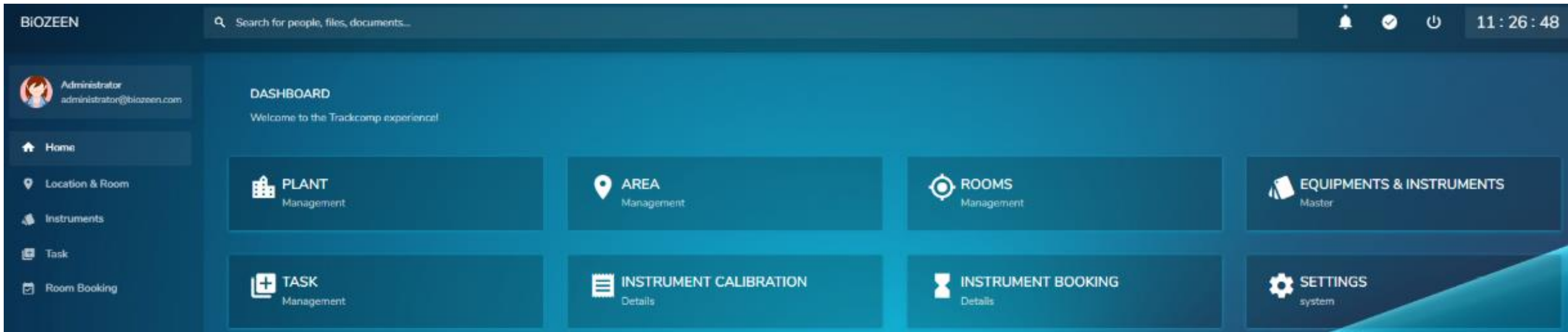
Digital Dashboard

Augmented Reality (AR)

Quality / Test automation through $AD\Sigma\Omega$

Sensor based data capture for CPP monitoring

Source: Industry 4.0, Reimaging manufacturing operations after Covid-19, McKinsey & Company

BiOZEEN PHARMA 4.0 – ADΣΩ DASHBOARD

- ❖ Materials Module (Automatic PO)
- ❖ Wearhouse Module (Logistics)
- ❖ Marketing Module (Sales- Business- Market Demand- Discount)
- ❖ Quality & Regulatory Module (e-BMR)
- ❖ Broadcasting Module (Selective Alerts)
- ❖ Personnel Management (Wearables)
- ❖ Virtual Management (Video and Batch Trend Comparisons)

BiOZEEN – GOING PAPERLESS

Why are we doing this?

❖ Audit ready – in real time

❖ Collaborate - in real time

❖ Electronic Signature – in real time

❖ Electronic Audit Trial

❖ Digital Reports

❖ Standardized Qualification Protocols across vendors

BiOZEEN – GOING PAPERLESS

All activities of validation are then prepared and executed through the paperless e-validation software – <u>without ever going to paper.</u>

- ❖ Design Qualification Protocol

- ❖ Manufacturing Protocols

- ❖ FAT Qualification Protocols

- ❖ Installation & Commissioning Reports

- ❖ SAT Qualification Protocols

- ❖ CSV

- ❖ Etc…

BiOZEEN – GOING PAPERLESS (SAMPLE)

Document Title	Functional Requirements Specification (FRS) for CE-690		
Document Number	FRS-CE-690	Document Version	0.1 In Development

Objective

This FRS document, FRS-CE-690 details the functional requirements for CE-690 for use at _____ in India

Review

Document Title	Performance Qualification (PQ)		
Document Number	PQ-01-4001	Document Version	2.1 In Review

Objective

PQ-01-4001 will verify that the system performs as expected under simulated real-world conditions and meets all release requirements for functionality and safety and that procedures are effective and reproducible.
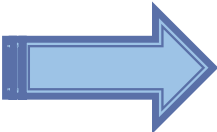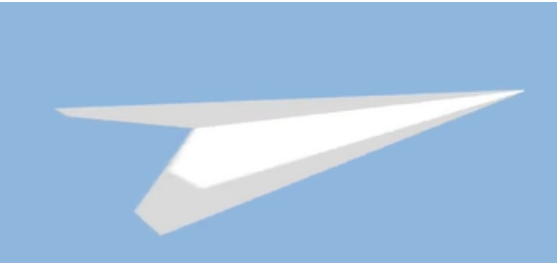
Test Cases

User Requirements Specifications (URS)	Functional Requ...
URS-001-EC12	FRS-063-HK15
URS-001-IL33	FRS-063-HK37
URS-001-EC01	FRS-063-OB06
URS-001-MS52	FRS-063-HK12

Add Comment ✕

Please add FRS-014-YT51 to FRS test cases list.

Insert   Cancel

Source: An e-validation software

BiOZEEN – GOING PAPERLESS (SUMMARY)

BiOZEEN's Scope

❖ Computer System e-Validation

❖ Commissioning & Qualification

❖ Equipment e-Validation

Opportunities for the Client

❖ Process e-Validation

❖ Cleaning e-Validation

❖ Instrument e-Validation

❖ Utility & Facility e-Validation and others

Thank You !

For any queries contact us at

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