

From Quality Maturity to Quality Performance - Databased Insights

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2021 ISPE Advancing Pharmaceutical Quality – What's New, What's Next?

Boston, March 18, 2021



- 1 Introduction
- 2 Quality Management Maturity & Quality Performance
- 3 The Maturity Performance Link
- 4 Conclusions and Outlook



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OPEX research @ University of St.Gallen



Hosting Industry Exchange St. Gallen Operational Excellence Research Group



QC Lab Exchange Platform

Tailored Industry
Collaboration Projects

Quality Metrics & Quality Maturity Research

Collaboration with Associations

Continuous St. Gallen Operational Excellence Benchmarking of Sites and Quality Control Labs (around 390 production sites and 110 labs)

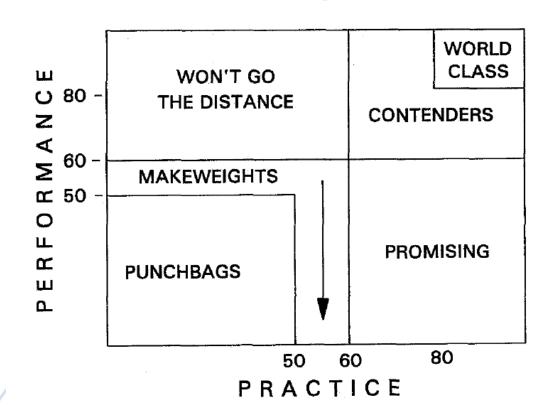
Research Priorities

Operational Excellence, Performance Measurement Systems, Maturity Assessment, Sustainable Improvements in Plants and Labs



Our Approach – Based on Science, verified with Real World Data





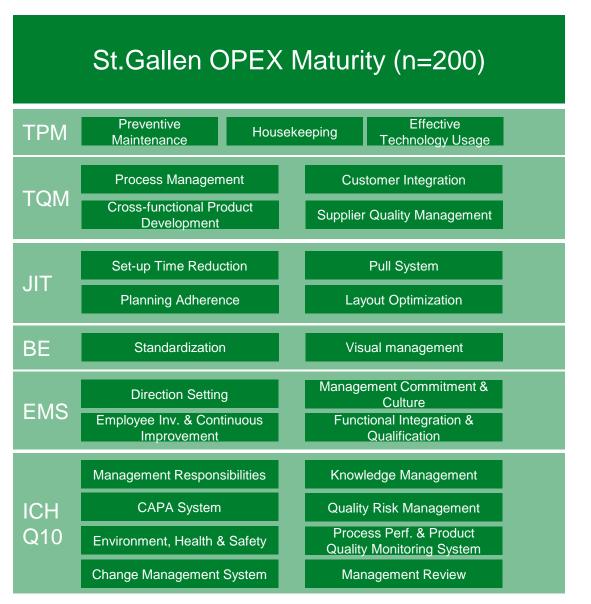
Source: Ferdows & De Meyer 1990; Voss et al. 1995

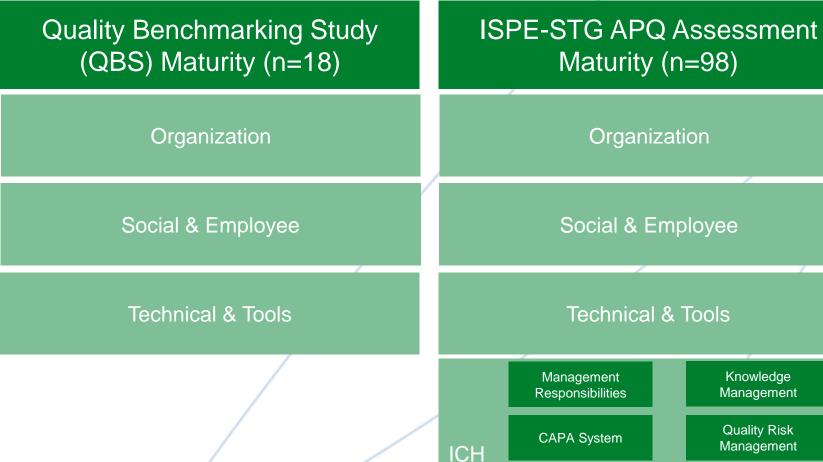




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Operationalization of Quality Management Maturity





Q10

Environment, Health

& Safety

Change

Management

System



Process Perf. &

Product Quality

Monitoring System

Management

Review

Operationalization of Quality Performance

1)Pharmaceutical Quality System (PQS) Effectiveness				
Aggregation 1	Aggregation 2			
Supplier Reliability				
Score				
	Aggregated PQS			
Operational Stability				
	Effectiveness Score			
Score				
	Aggregation 1 Supplier Reliability Score			

2) QBS & APQ Effectiveness Score
Unplanned Maintenance
Rejected Batches
Recurring Deviations
Quality FTEs/ Overall FTEs
iOOS Rate
Deviations Closure Time
Service Level (Delivery)
Service Level (Supplier)
Customer Complaint Rate
Adherence to Standard Lead Time
3) QBS Short Effectiveness Score
Unplanned Maintenance
Rejected Batches
Service Level (Delivery)



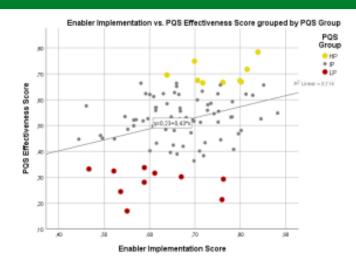
Deviation Closure Time



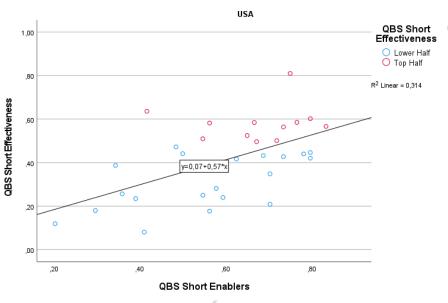
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- 2 Quality Management Maturity & Quality Performance
- 3 The Maturity Performance Link
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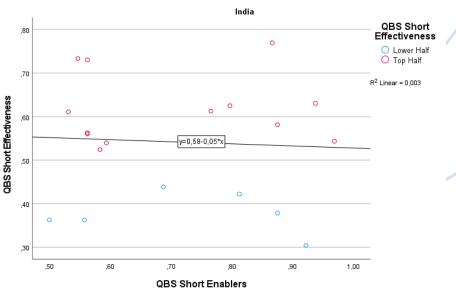
QMM – Performance Link

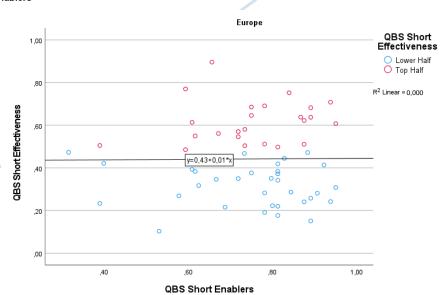
FDA Quality Metrics Research



Quality Benchmarking Study (QBS)









Quality Management Maturity, Performance & Compliance

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Group	QBS Short Effectiveness	QBS Short Enablers	Compliance Score*
High Effectiveness/ High Maturity	.60	.76	.40
High Effectiveness/ Low Maturity	.55	.58	.50
Low Effectiveness/ High Maturity	.38	.75	.34
Low Effectiveness/ Low Maturity	.28	.47	.36

Europe

Group	QBS Short Effectiveness	QBS Short Enablers	Compliance Score*
High Effectiveness/ High Maturity	.61	.81	.41
High Effectiveness/ Low Maturity	.62	.59	.00
Low Effectiveness/ High Maturity	.32	.88	.25
Low Effectiveness/ Low Maturity	.31	.54	.34

India

Group	QBS Short Effectiveness	QBS Short Enablers	Compliance Score*
High Effectiveness/ High Maturity	.62	.87	.50
High Effectiveness/ Low Maturity	.60	.56	.20
Low Effectiveness/ High Maturity	.36	.86	.34
Low Effectiveness/ Low Maturity	.38	.58	.00





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Towards a Comprehensive Site Evaluation

