

From Quality Maturity to Quality Performance - Databased Insights

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

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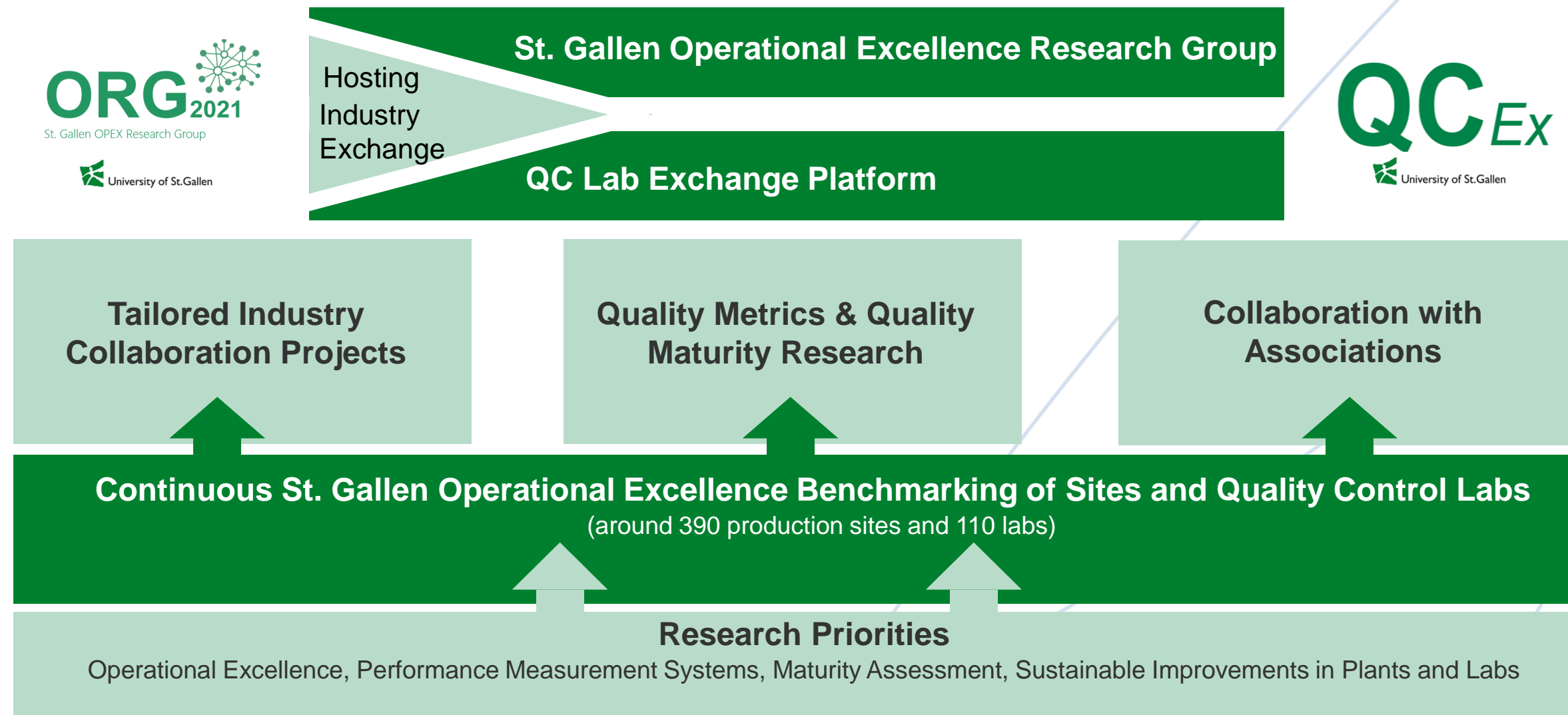
Agenda

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

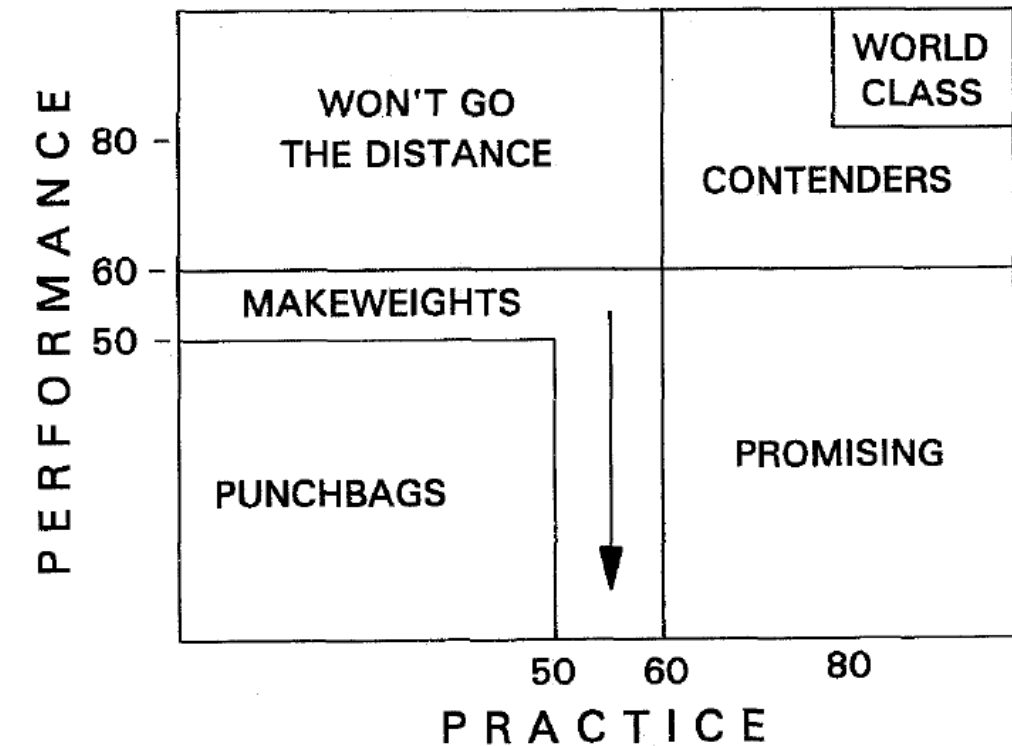
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OPEX research @ University of St.Gallen



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



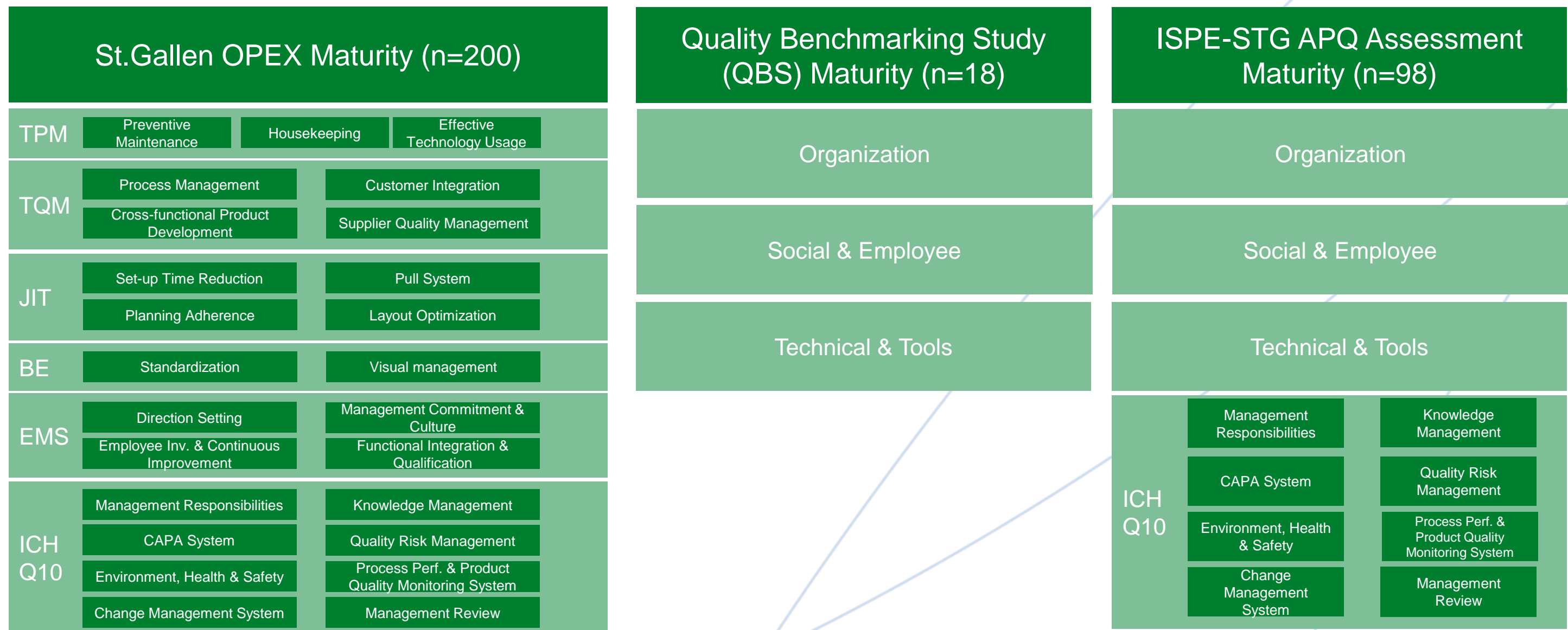
Source: Ferdows & De Meyer 1990; Voss et al. 1995



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Operationalization of Quality Management Maturity



Operationalization of Quality Performance

1) Pharmaceutical Quality System (PQS) Effectiveness

KPI	Aggregation 1	Aggregation 2
Complaint Rate (Supplier)	Supplier Reliability Score	Aggregated PQS Effectiveness Score
Service Level (Supplier)		
Unplanned Maintenance	Operational Stability Score	
Overall Equipment Effectiveness		
Rejected Batches		
Deviations/ Batch		
Yield		
Scrap Rate		
Release Rate		
Deviation Closure Time		

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)

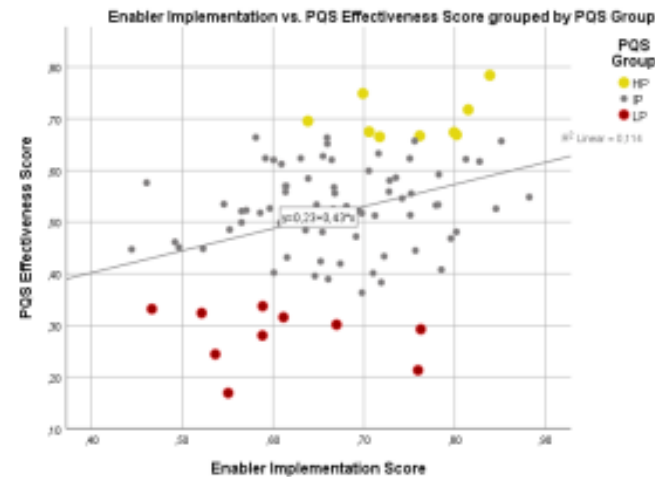


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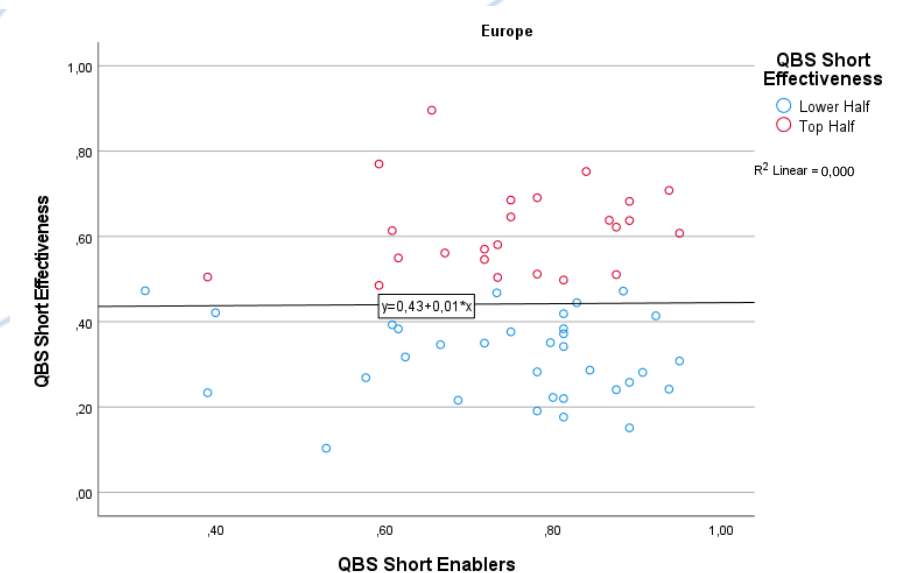
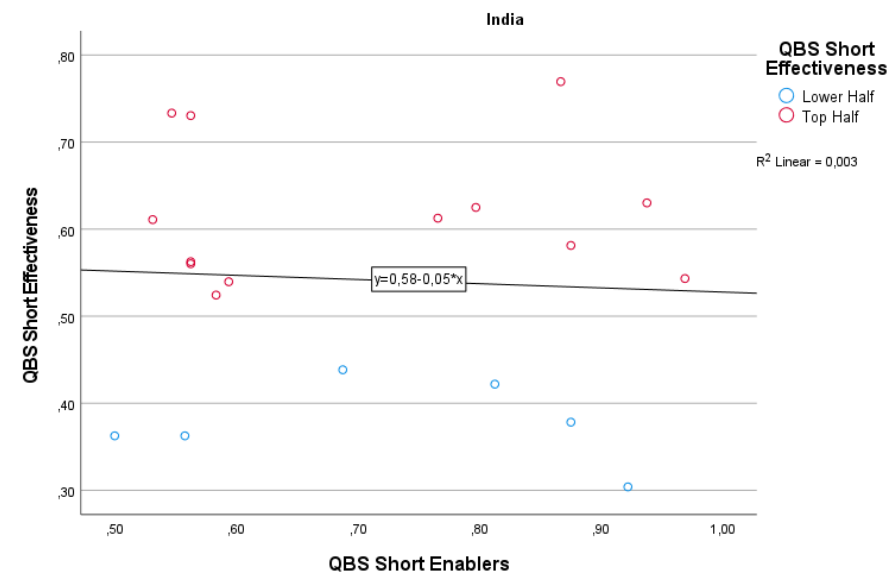
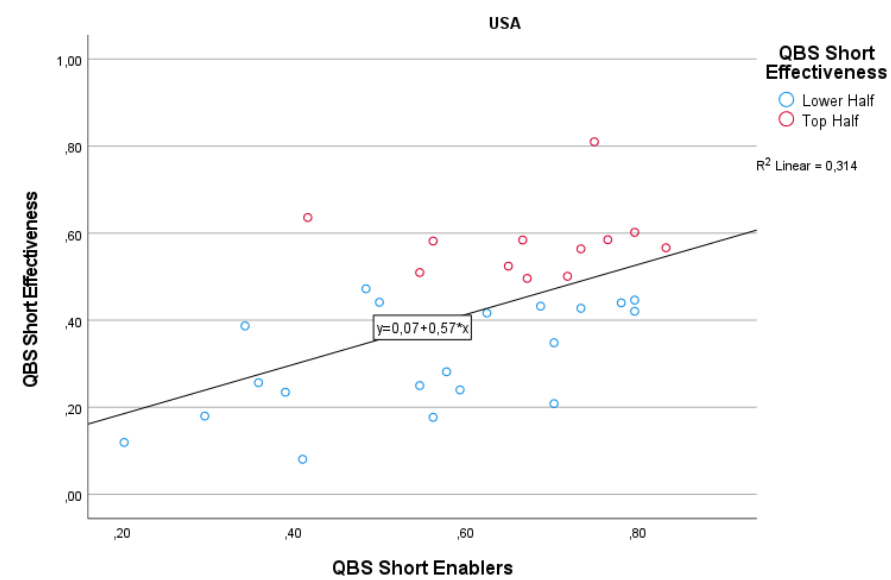
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QMM – Performance Link

FDA Quality Metrics Research



Quality Benchmarking Study (QBS)



Quality Management Maturity, Performance & Compliance

USA	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

