

Operational Excellence ***Quality Control Lab Benchmarking***

Personalized Report

Illustrative report extract - does not contain all pages and no real

Preface

Dear participant,

The Quality Control Lab Benchmarking on Operational Excellence (OPEX) is based on the St.Gallen reference model for quality control labs that was established in 2016 (figure 1). The model addresses the demand of a comprehensive OPEX analysis of your quality control lab. The approach combines a performance assessment on productivity, quality and service level with a maturity assessment of your OPEX activities regarding your maintenance & quality system, planning & steering system as well as your management system.

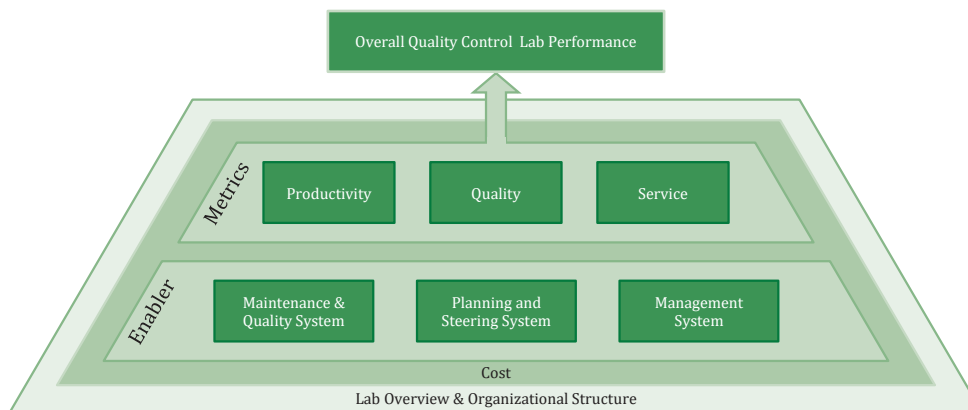


Figure 1: St.Gallen reference model for quality control labs

With this personalized report you are able to compare your Operational Excellence Performance and Maturity with your peer group. The database currently encompasses 33 labs from multiple pharmaceutical companies from all over the world.

Based on this report we can help you to derive your next steps on the journey to Operational Excellence. If you have any questions, please do not hesitate to contact the St. Gallen OPEX Team.

St. Gallen, July 2018

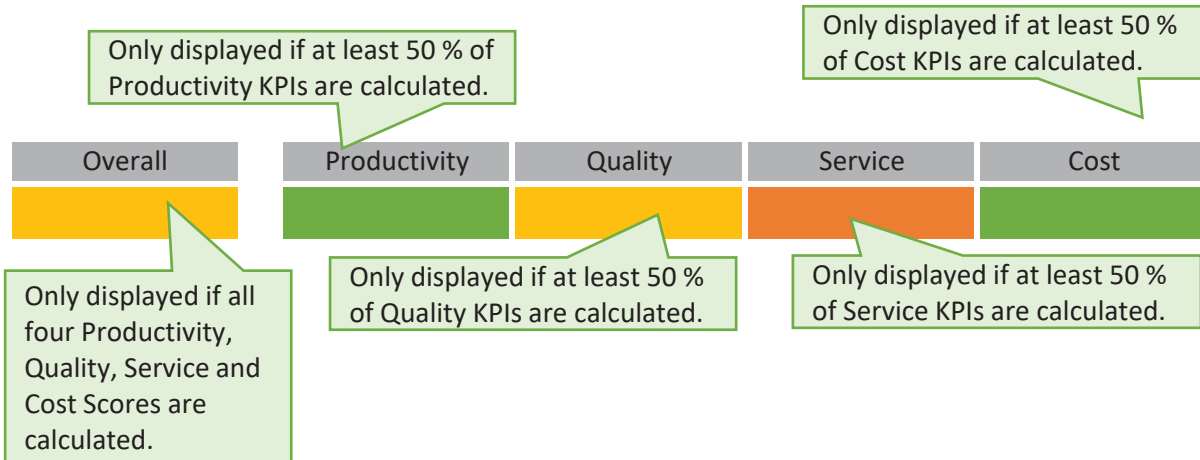
Prof. Dr. Thomas Friedli
Institute of Technology Management

Table of Content

1. Terms and Explanations	4
2. Management Summary	6
3. Database Structure	8
4. Your Peer-group	11
5. Lab Overview	14
6. Organizational Structure	17
7. Performance	19
7.1 Productivity	19
7.2 Quality	21
7.2 Service	24
8. Cost Structure & Efficiency	27
9. Enabler	29
9.1 Maintenance & Quality System	29
9.2 Planning & Steering System	33
9.3 Management System	36
10. Contact Details	39
11. Appendix	40

1. Terms and Explanations

Management Summary



Calculation

The Productivity, Quality, Service and Cost Scores are calculated based on all KPIs from each section in the Management Summary. The Overall Score is an average of all individual Performance Scores. The categories Productivity, Quality, Service and Cost are equally weighted.



Heat maps

Peer median and HP values are only displayed if KPI is calculated from a number of labs equal to or greater than 3.
Heat maps only displayed if number of labs is equal or greater than 5.

If you belong to the Top25% for this KPI it is green. Further details provided in key.

High Performer value represents the average value of the Top25% labs based on the Overall Performance Score.

If you do not provide data, no median and HP-value is shown.

Definitions for all KPIs can be found in the Appendix.

	Unit	Your value	Peer Median	HP
Reporting Layers	No.	3	3	2
Employees Fluctuation	%	n/a	5%	3%
Cross-trained Analysts	%	n/a	36%	95%
Group A	%	n/a	n/a	n/a
Tr	Days	n/a	n/a	n/a
Sick Leave	%	3%	7%	2%



Example

You provided the value 3 for "Reporting Layers". The peer median is also 3. The high performer value which represents the average value of the Top25% labs (based on the Overall Performance Score) is 2. With this result you are in the 2nd Quartile meaning at least 25% are better than you but also at least 50 % have a value that is worse than yours (3rd and 4th Quartile).

2. Management Summary

Performance

Overview

Overall	Productivity	Quality	Service	Cost

Your Overall Lab Performance totals at 54 %. You belong to the 2nd Quartile. 54 % of your peer-group have a lower Overall Lab Performance than your Quality Control Lab. 46 % have a higher Overall Lab Performance than you.

Productivity

	Unit	Your value	Peer Median	HP
Handled Samples/QC FTEs	No./FTE	484	243	271
Batches processed/QC FTEs	No./FTE	78	118	160
Tests/Direct QC FTEs Overall	No./FTE	1'219	1'219	1'532

Quality

	Unit	Your value	Peer Median	HP
Lab Deviations/1'000 Tests	No.	1.9	1.8	0.1
Reoccurring Lab Deviations	%	3.7%	3.0%	1.0%
Lab CAPAs Overdue	%	0.9%	1.0%	1.3%
Overall RFT	%	98.1%	93.5%	95.9%
Overall Invest./1'000 Tests	No.	1.5	3.3	2.7
Overall Inv. OOS/100'000 Tests	No.	201.5	186.2	113.1
Prod. Re-Tests due to Complaints	%	0.0%	0.0%	0.1%

Service

	Unit	Your value	Peer Median	HP
Average Lead Time	Days	20	18	11
Average Cycle Time	Days	11	14	9
Average Release Time	Days	16	9	4
Average Adherence to Schedule	%	n/a	n/a	n/a
Average Adherence to Lead Time	%	91%	91%	95%

Cost

	Unit	Your value	Peer Median	HP
QC Costs/Total QC FTEs	EUR/FTE	83'485	53'776	40'492
QC Costs/Total No. of Tests	EUR/Test	117	61	40

KEY

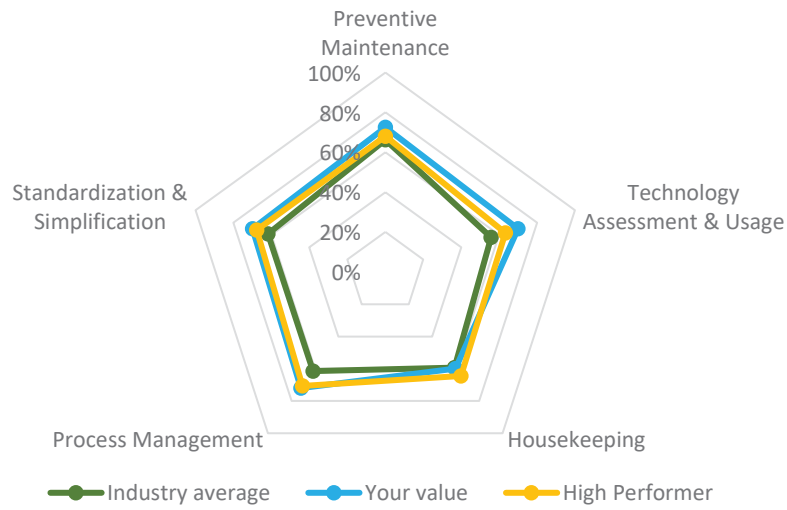
Top Quartile

2nd Q

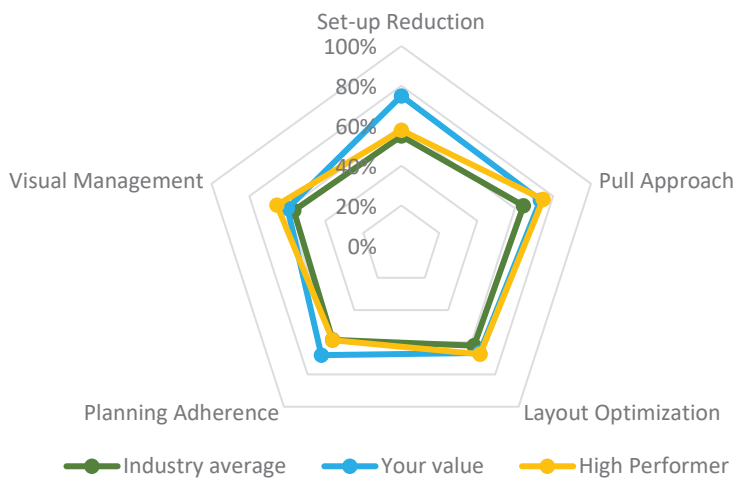
3rd and 4th Q

Enabler

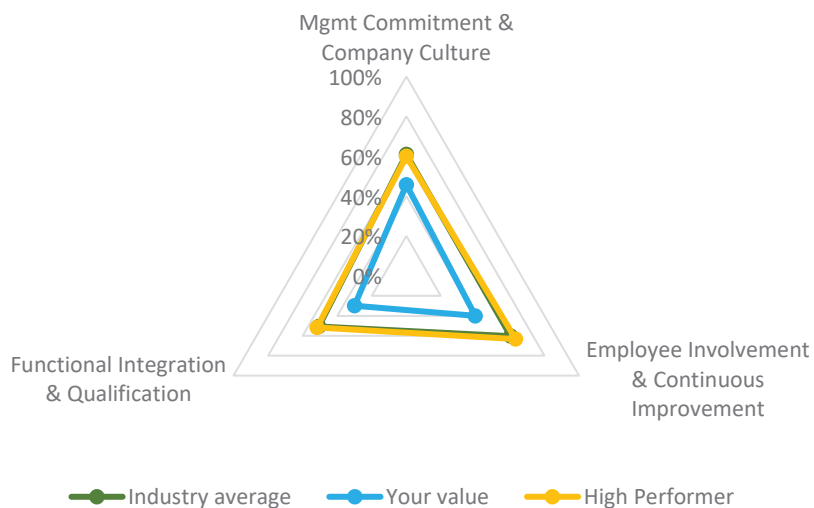
Maintenance & Quality System



Planning & Steering System



Management System



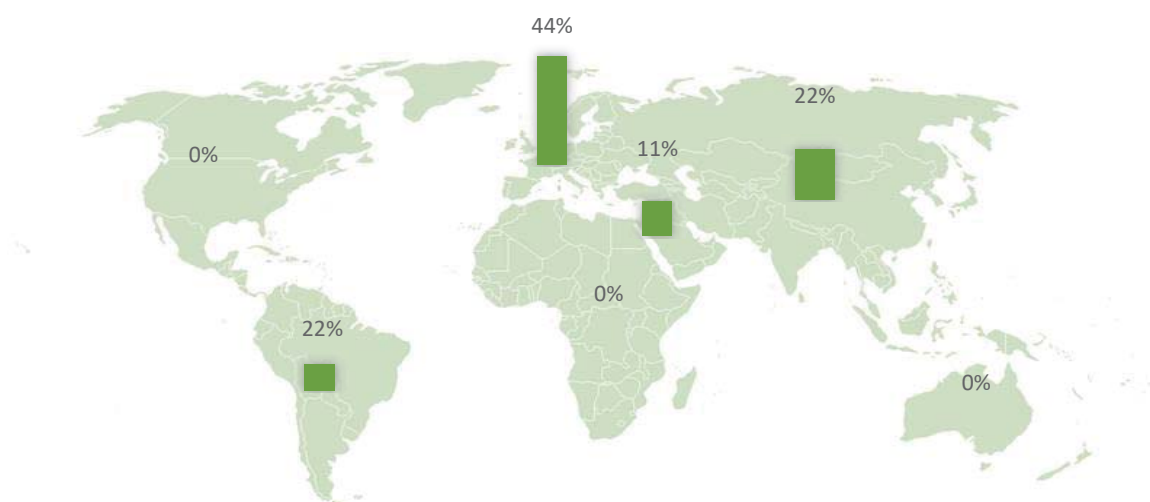
4. Your Peer-group

Your QC Lab Benchmarking peer-group comprises in total 12 labs of different pharmaceutical companies. This chapter begins with an overview of the selected filter for your peer-group followed by a detailed overview of the peer-group characteristics.

Applied Filters

Filter	Specification			
Included Labs (from year...)	No filter applied			
Country	No filter applied			
Region	No filter applied			
High Cost vs. Low Cost	No filter applied			
Drug Substance Type	Any drug substance			
Drug Product Type	No filter applied			
No. of Drug Products	Min	-	Max	-
Multi-purpose Lab	Yes	-	No	-
Centralization	No filter applied			
Degree of Centralization	Min	-	Max	25%
Proportion of 3rd Party testing	No filter applied			
Total Site FTEs	Min	-	Max	-
Total QC FTEs	Min	-	Max	-
Total no. of Batches processed	Min	-	Max	-
Handled Samples	Min	-	Max	-
Total no. of Tests	Min	-	Max	-
Regulatory Approval	Only labs with regulatory approval			

Regional Distribution of Labs



Africa	n/a	Middle and South America	22%
Asia	22%	Middle East	11%
Europe	44%	Oceania	n/a
North America	n/a		

6. Organizational Structure

General Metrics

	Unit	Your value	Peer Median	HP
Span of Control	No.	8	13	11
Reporting Layers	No.	3	3	5
Qualified Technicians	%	100%	78%	49%
Employees Fluctuation	%	8%	5%	3%
Cross-trained Analysts	%	95%	87%	80%
Group Work	%	n/a	n/a	n/a
Training	Days	n/a	n/a	n/a
Sick Leave	%	3%	5%	3%
Number of Suppliers	No.	5	29	26

KEY

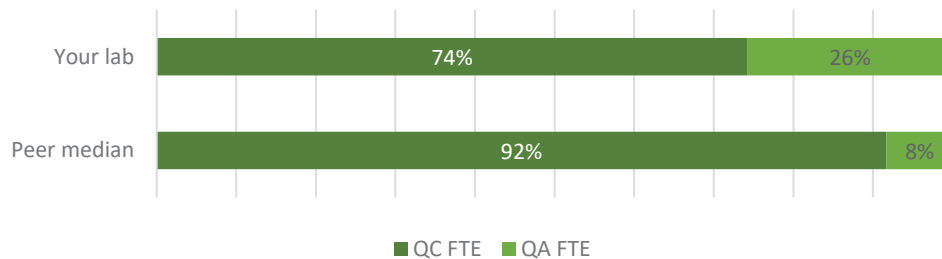
Top Quartile

2nd Q

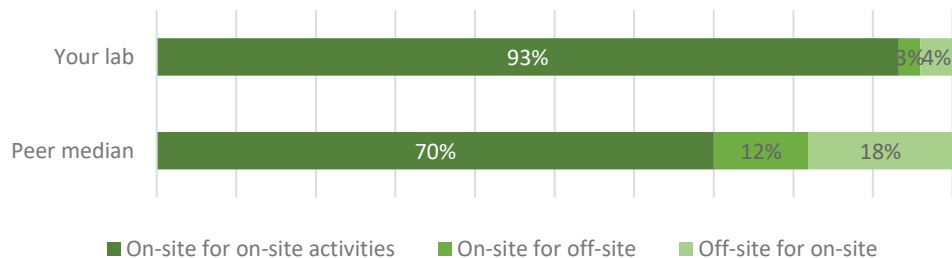
3rd and 4th Q

FTE Structure

Split between QC and QA FTE



QA On-Site vs. Off-Site activities



7.2 Quality

General Metrics

	Unit	Your value	Peer Median	HP
Lab Deviations/1'000 Tests	No.	1.9	1.8	0.1
Reoccurring Deviations	%	3.7%	3.0%	1.0%
CAPAs Overdue	%	0.9%	1.0%	1.3%
CC* Investigation/100'000 Tests	No.	8	4	4
Re-Tests due to Complaints	%	0.00%	0.00%	0.12%
APQR/Products tested	No.	0.11	1.06	2.23
APQR On-time Rate	%	n/a	n/a	n/a
Batches/Change Controls	No.	8	43	41
Batches/Audits	No.	1'189	3'184	3'184
Batches/Method Transfers	No.	1'030	424	408
Batches/Method Validations	No.	92	121	112
Stability Batches/Stab. Reports	No.	n/a	n/a	n/a

* CC = Customer Complaint

Right First Time

	Unit	Your value	Peer Median	HP
Overall RFT	%	98.1%	93.5%	95.9%
Drug Substance	%	99.7%	88.3%	92.7%
Intermediate	%	99.8%	97.0%	n/a
In Process Control	%	n/a	n/a	n/a
Raw Material	%	99.8%	91.0%	n/a
Stability	%	n/a	n/a	n/a
Drug Product	%	91.0%	91.5%	92.0%
Packaged Product	%	n/a	n/a	n/a
Microbial Environmental	%	100.0%	99.9%	n/a
Microbial Product	%	n/a	n/a	n/a
Component & Packaging	%	n/a	n/a	n/a

KEY

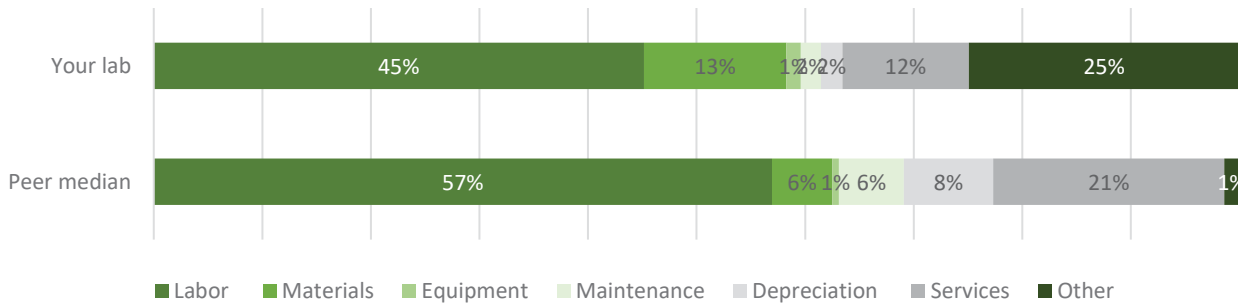
Top Quartile

2nd Q

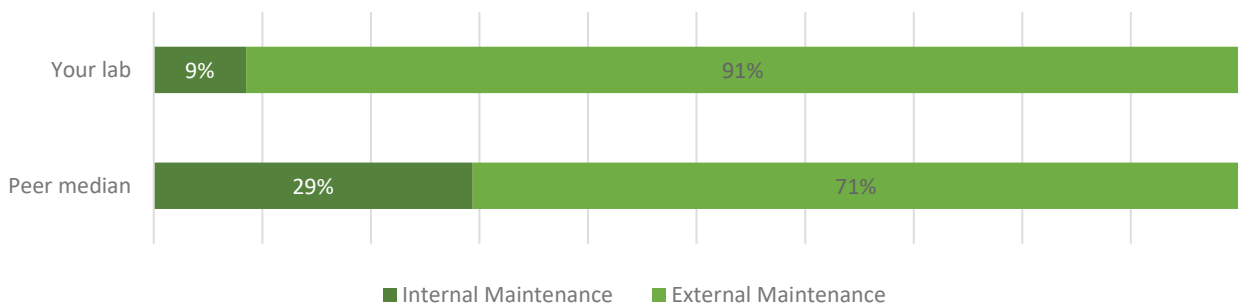
3rd and 4th Q

8. Cost Structure and Efficiency

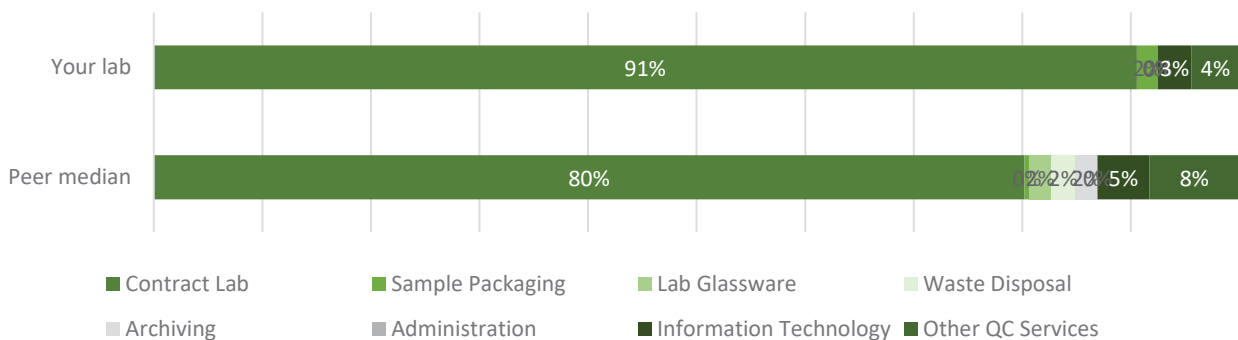
QC Cost Distribution



QC Maintenance Cost Split

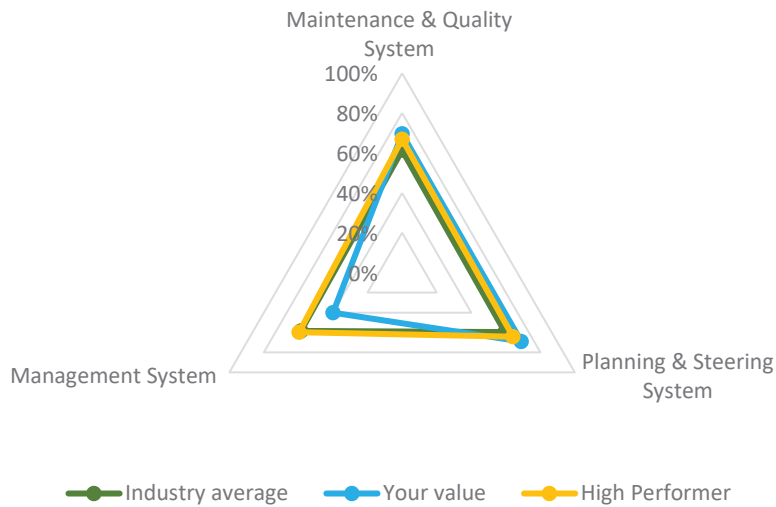


QC Service Cost Split



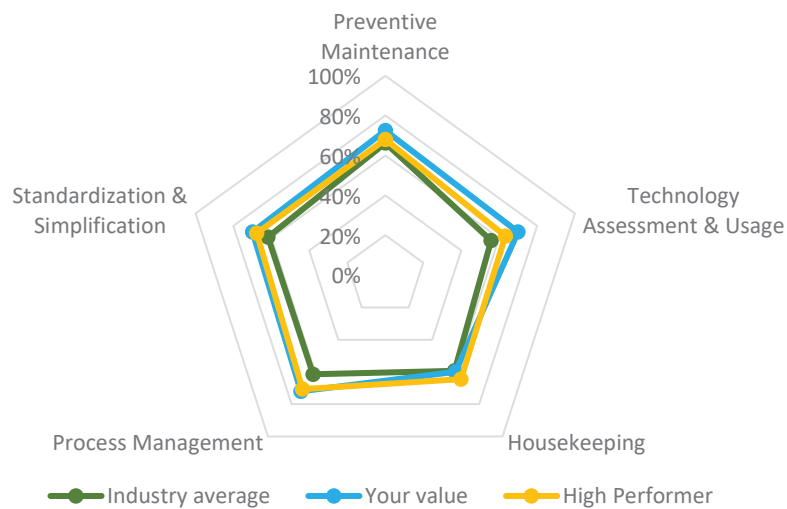
9. Enabler

Overall Overview



9.1 Maintenance & Quality System

Overview



Preventive Maintenance



10. Contact Details

Address

University of St.Gallen
Institute of Technology Management
Dufourstrasse 40a
9000 St. Gallen
Switzerland

Contact

Stephan Koehler
+ 41 71 224 72 71
stephan.koehler@unisg.ch

Website

www.tectem.ch
www.item.unisg.ch