qFMEA for the QMS

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- ✓ Define Risk
- ✓ Discuss the Risk Management Process
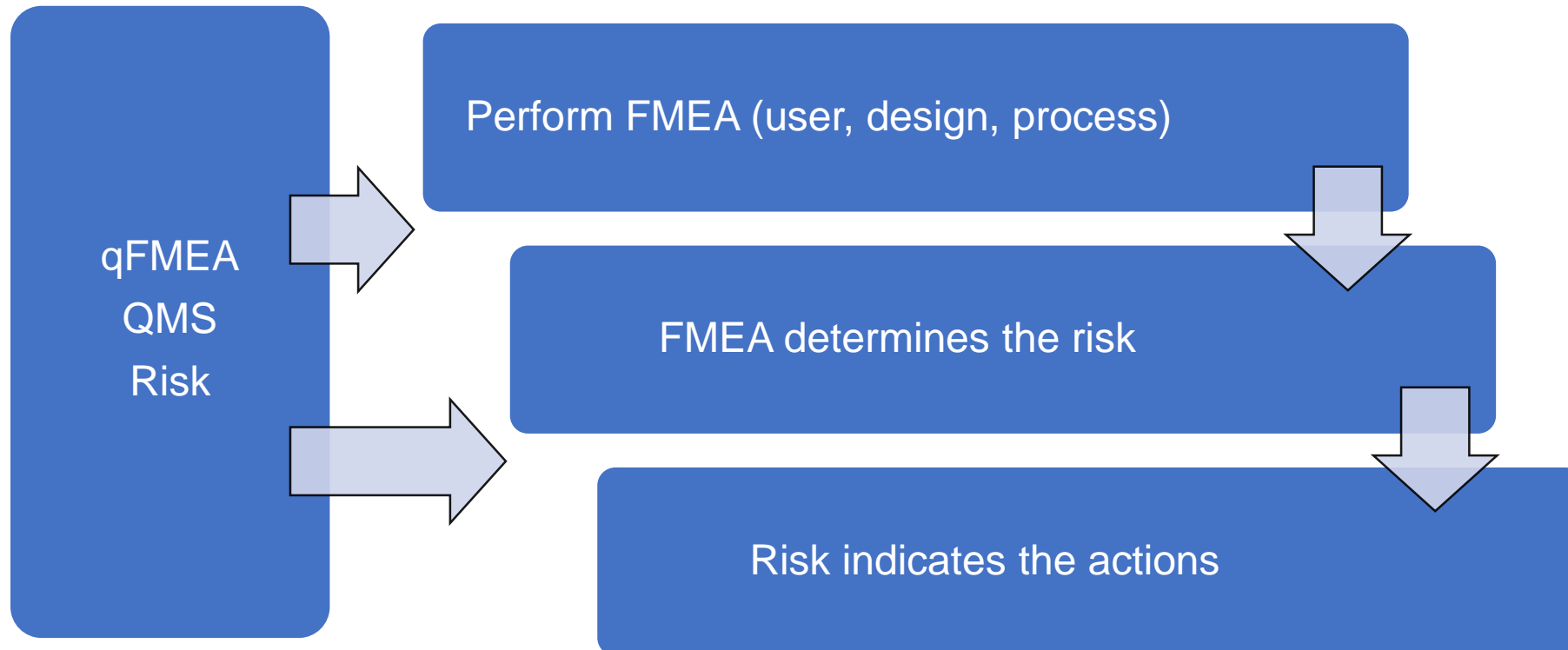- ✓ Define Risk-Based Thinking
- ✓ Introduce qFMEA

RISK

Failure Mode and Effects (FMEA) Analysis

qFMEA
QMS
Risk

Perform FMEA (user, design, process)

FMEA determines the risk

Risk indicates the actions

qFMEA Ratings

➢ Compliance Risk Rating (CRR)

➢ Requirement Maturity Rating (RMR)

➢ Internal Audit Effectiveness (IAE)

Compliance Risk Rating (CRR)
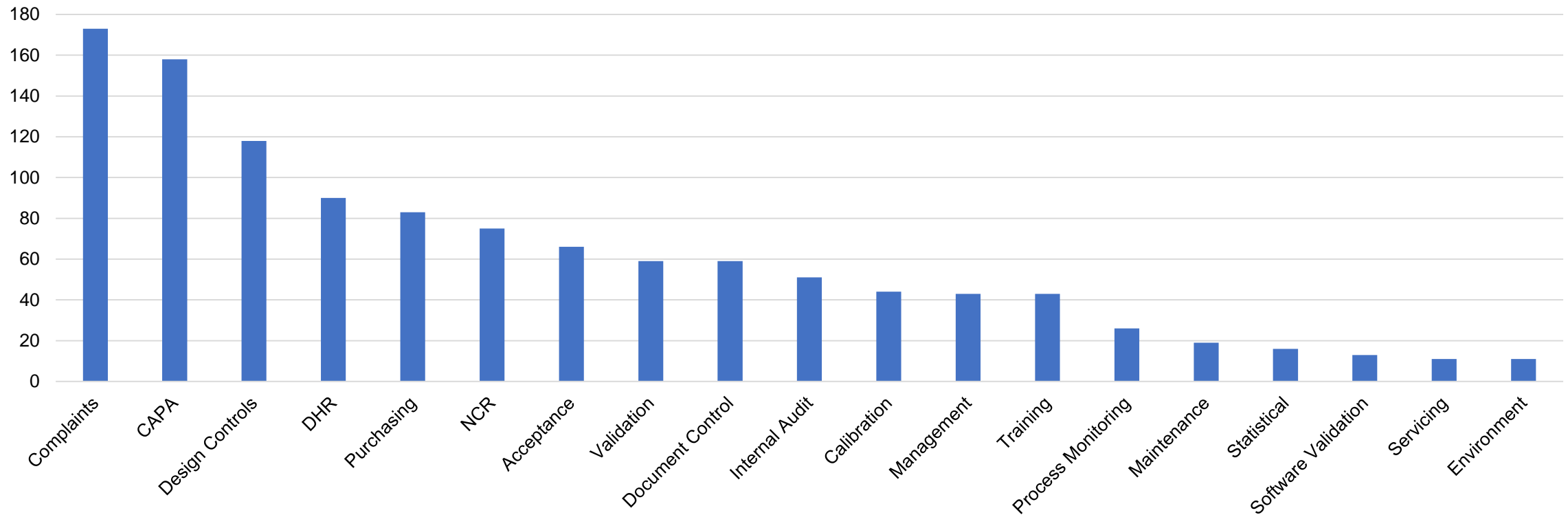
5	Very high	Certain
4	High	Expected
3	Medium	Likely
2	Moderate	Unlikely
1	Low	Doubtful

Compliance Risk Rating (CRR)

483 Citations Pareto Analysis

Compliance Risk Rating (CRR)

Part 820 Quality System Regulation for Medical Devices		
820.25	Personnel.	3
820.50	Purchasing controls.	4
820.60	Identification.	1
820.100	Corrective and preventive action.	5
820.250	Statistical techniques.	2

Requirement Maturity Rating (RMR)

May 31-June 1, 2017

5	Ad hoc	Informal process
4	Developing	Semiformal process
3	Defined	Formal process
2	Managed	Integrated formal process
1	Continuous	Process optimization

5	Poor	Informal process
4	Below average	Semiformal process
3	Average	Formal process
2	Good	Integrated formal process
1	Excellent	Process Optimization

Internal Audit Effectiveness (IAE)

RPN Action Requirements

RPN	Risk Acceptability	Action
1 to 14	Low	Although low risk, risk should be periodically reviewed for reduction opportunities.
15 to 29	Tolerable	Risk should be periodically reviewed for reduction opportunities.
30 to 49	Undesirable	Risk is acceptable only if it cannot be further mitigated by organizational or technological solutions.
Above 49	Intolerable	Risk should be further reduced. Justification required for risk that is accepted.

CMR					
RMR		Very High	High	Medium	Moderate	Low
		5	4	3	2	1
Ad hoc	5	Unacceptable	Unacceptable	Unacceptable	Unacceptable	ALARP
Developing	4	Unacceptable	Unacceptable	Unacceptable	ALARP	ALARP
Defined	3	Unacceptable	Unacceptable	ALARP	ALARP	ALARP
Managed	2	Unacceptable	ALARP	ALARP	ALARP	Acceptable
Continuous	1	ALARP	ALARP	ALARP	Acceptable	Acceptable

*ALARP - As Low as Reasonably Possible

Compliance Maturity Rating and Requirement Maturity Rating Action Requirements
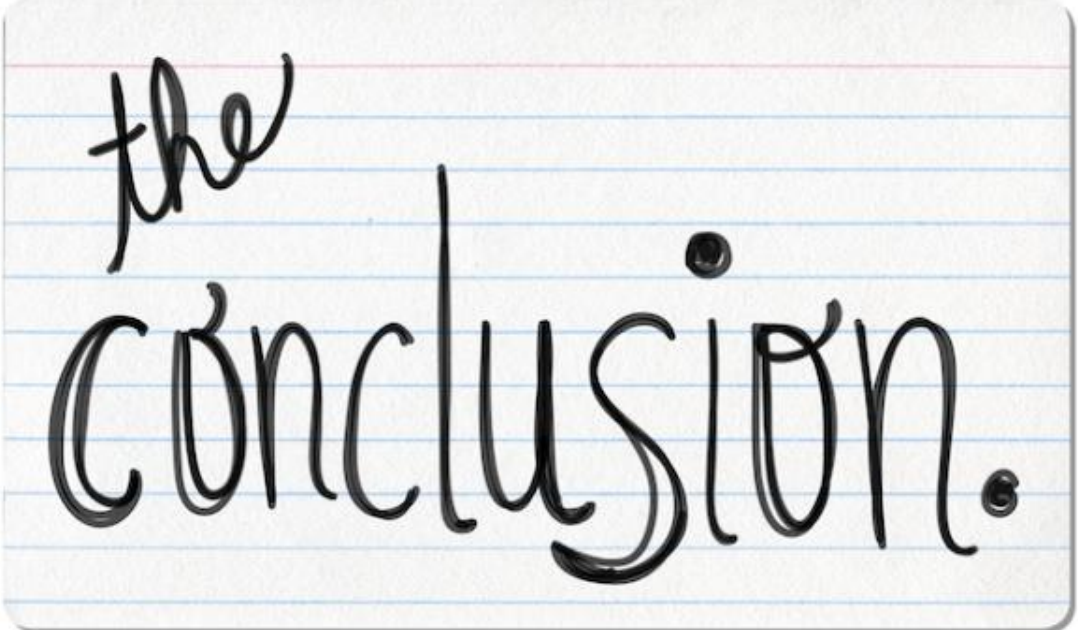
Risk Priority Numbers

$$RPN = CRR \times RMR \times IAE$$

	Compliance Maturity	Requirement Maturity	Internal Audit Effectiveness	RPN
820.50	4	4	3	48

ITEM	FUNCTION	C R R	R M R	I A E	R P N	EVALUATION	ACTIONS TAKEN	C R R	R M R	I A E	R P N
820.50	Purchasing controls.	4	4	3	48	risk acceptability is undesirable	1) hire a consultant 2) send SQE for training	4	2	3	24

- ➢ Use risk management tools that are appropriate to your organizations expertise
- ➢ Proceduralize the risk management tools your organization utilizes.
- ➢ Keep apprised of current industry trends
- ➢ Document you plan, actions, and results

Questions

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Quality Systems Compliance LLC