

CRPN Quality Roadmap[™] **Methodology & Hosted Application**

Quantifying FDA Compliance Risk
and Remediation Complexity
to *Structure and Improve*
Quality Planning and Remediation Outcomes

What is the *CRPN Quality Roadmap*™

The *CRPN Quality Roadmap*™ is a structured consulting service offering comprised of a defined, proven methodology, proprietary risk and complexity algorithms, and cloud-based software tool that together facilitates intelligent, semi-quantitative, risk-based planning for regulated, life-science manufacturers.

CRPN Quality Roadmap™ Use Applications

- Quality Improvement Program Development
- Capital Projects Planning and Portfolio Analysis
- Audit Response Plan Prioritization
- Quality Operations Strategic Planning
- Compliance Risk Reduction Program Planning
- Quality Activities Portfolio Analysis and Resource Assignments
- CAPA Risk, Remediation and Resource Planning
- Complex Enforcement Remediation Planning
- Executive Stakeholder Financial Planning Alignment Discussions
- Process Improvement Planning

CRPN Quality Roadmap™ Benefits

- Alignment of stakeholders on risk considerations, using a formal, structured methodology for quantifying FDA compliance enforcement risk
- Algorithms transform **qualitative** risk information and assumptions into **quantitative** data for compliance risk reporting and comparability purposes
- The method and tool introduces a novel *complexity* factor into planning to facilitate resource considerations and organizational capability
- The easy-to-use software tool that allows regulated life-science manufacturers to develop data-driven quality and remediation plan documents for capital and expense budgeting and project resource prioritization planning

Overview of Methodology / Approach

Typical Timeframe: Two to Six Months

Collect and
Assess Issues,
Risks, Gaps,
Projects

Risk Prioritize
Gaps and
Issues; Assess
Complexity

Develop,
Prepare and
Communicate
Output
Reports

Automate &
Operationalize
Planning
Capability
(*Optional*)

Enabling Capability - Risk

- Our methodology establishes an algorithmic determination of **relative** compliance risk, across a portfolio of risks, derived from assigning objective, weighted measures to subjective compliance risk factors

- Compliance Risk Prioritization Number (CRPN) =

$$f(\textit{Gap Size}, \textit{Detectability}, \textit{Enforcement Response})$$

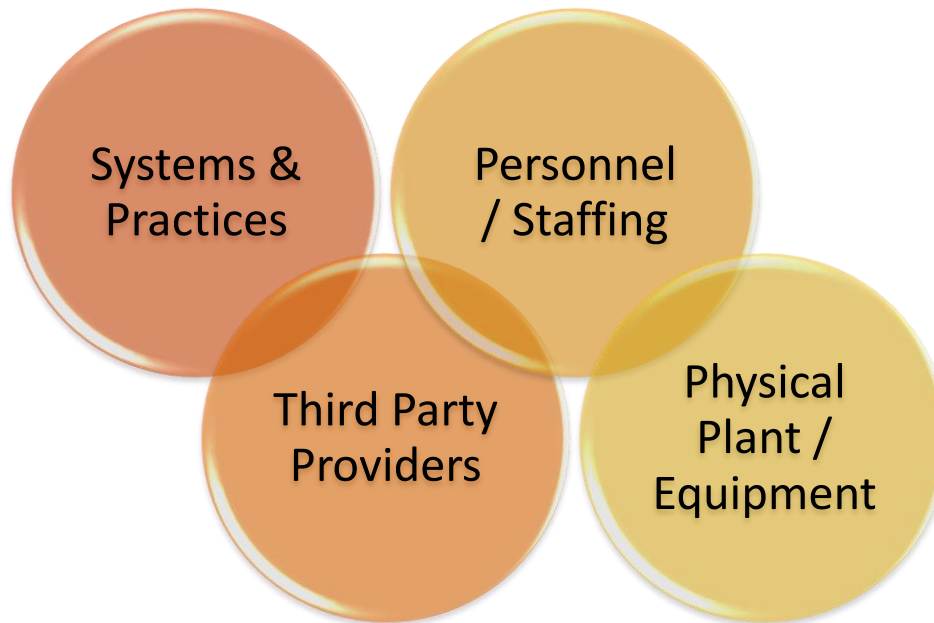
- Basic algorithm and factors are pre-established but may be adjusted based on client's enterprise risk criteria
- Relative risk is normalized to a 0 – 100 scale to ensure sufficient differentiation across a risk-set portfolio

Enabling Capability – Complexity

- The Complexity Factor is an algorithmic determination of organizational complexity and cost, derived from assigning objective, weighted measures to subjective organizational complexity factors, such as estimated remediation cost, departments involved, time to remediate, etc.
- It is designed to assess cost, organizational and project completion duration factors in the context of remediation priority and compliance risk
- It is important for resource support identification, ownership, and funding actions
- By combining with the CRPN, helps to determine organizational focus priority
- Quantifies “low hanging fruit” perceptions

Charting and Reporting

- Reporting options are highly flexible and can be configured to meet customer needs and reporting requirements
- Charts and chart formats are flexible to provide best visualization for stakeholder engagement
- Additional metadata can be added to risk / gap / project designations to sort by different classifications, such as:



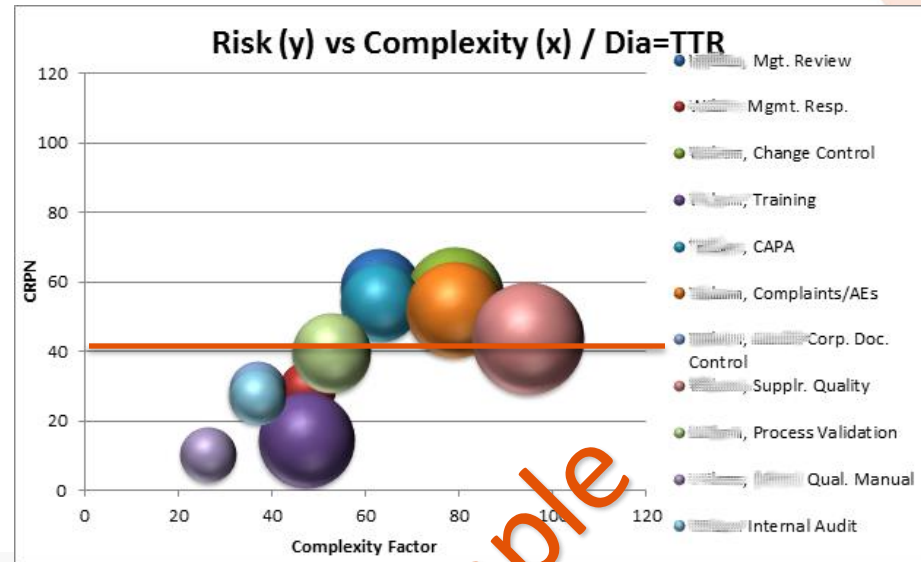
These groupings can provide top-level buckets for drill-down into issues, observations and activities.

Known Issues and Gaps -
Product and Process
Quality System, etc.

Deviations
Non-Conformances
Complaint Trends

Existing
CAPAs /
Projects

Output Enables Plan Development



CONSULTING • TECHNOLOGY • OUTSOURCING

CAP Site • Compliance Assessment Issues • CRPN Summary View

This list contains the issues resulting from a general compliance assessment.

Compliance Architects Client Portal / CAP Site QS Remediation Resource Management

Compliance Issues
Lists

Compliance Assessment
Issues

Risk Mgt / DHF Issues

Lookup Lists

Site Names

QSR Titles

Products

DHF Sections

Compliance Projects
& Charts

CAP Projects

Charts



Issue Description

Mgt. Review

Mgmt. Resp.

Change Control

Training

CAPA

Complaints/AEs

Corp. Doc. Control

Supplr. Quality

Process Validation

Qual. Manual

Internal Audit

+ Add new item

CRPN

58

29

56

15

54

52

29

44

40

10

27

Complexity Factor

Related QSR area

63 Management Responsibility

47 Management Responsibility

79 Design Controls - Design Changes

47 Personnel

63 CAPA

79 Complaint Files

37 Document Controls

95 Purchasing Controls

53 Process Validation

26 Management Responsibility

37 Quality Audit

Quality Strategic Plan Development



Key Quality Systems Enablers for the Company Business Strategy

Process Validation CRPN > 40

Enables:

- new product introduction
- cost effective, robust product supply

Change Control CRPN > 40

Enables:

- critical changes for products designated "breakthrough therapy" launched prior to completion of full process development characterization and validation
- cost effective, robust product supply
- reduction in product quality complaints due to process variability or low cPk

Supplier Quality CRPN > 40

Enables:

- introduction of new products requiring technologies outside of company core capabilities
- cost effective, robust product supply
- reduction in product quality complaints due to process variability or low cPk at suppliers/third party manufacturers

Key Disablers (Q&C Risks) for the Company Business Strategy

Management Review CRPN > 40

Prevents:

- FDA enforcement actions
- market actions due to product safety and/or quality issues

Complaints/Adverse Events CRPN > 40

Prevents:

- market actions due to product safety and/or quality issues

Internal Audits CRPN > 40

Prevents:

- FDA enforcement actions
- market actions due to product safety and/or quality issues

Example



The *CRPN™ Quality Roadmap* methodology and software is available exclusively through Compliance Architects LLC.

For further information, please contact Compliance Architects® at 888-734-9778, or via email at info@compliancearchitects.com