2023

Selecting the Right Supplier:

Suppliers as Critical Assets for Sourcing Decisions

USP <1083> Supplier Qualification

Maria Barbosa | May 30th, 2023

Bial
Keeping life in mind.

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Agenda

- Purpose
- Supplier Qualification in the Pharmaceutical Industry
- Background
- Supplier Qualification Life Cycle
- Supplier Qualification: European Guidelines vs FDA Guidelines
- Challenges

Purpose

Supplier Qualification in the Pharmaceutical Industry

Background

38(2)
[Mar.–Apr. 2012]

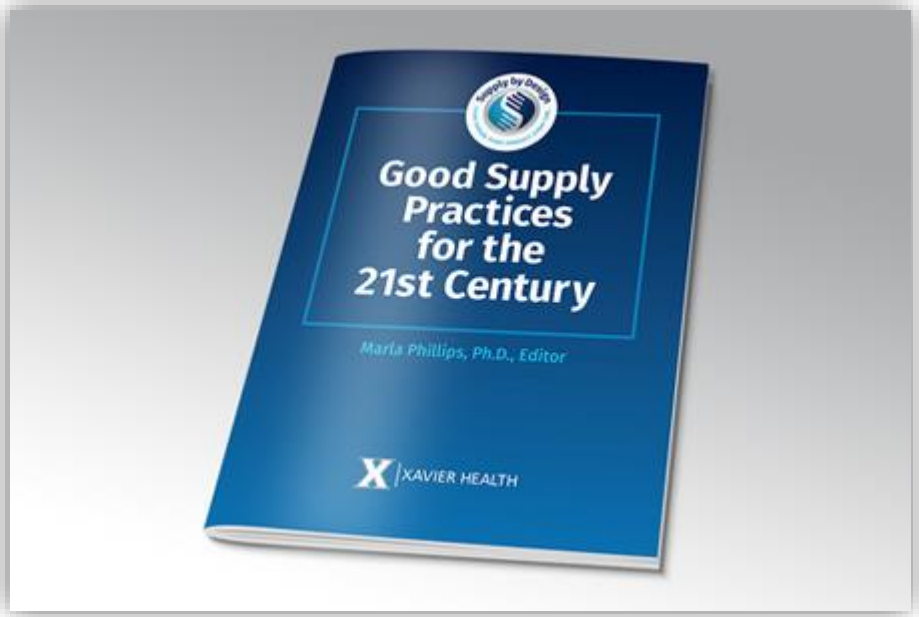
40(2)
[Mar.–Apr. 2014]

Background

Good Supply Practices for the 21st Century

USP <1083> Supplier Qualification

will officially come into force on 01 August 2023



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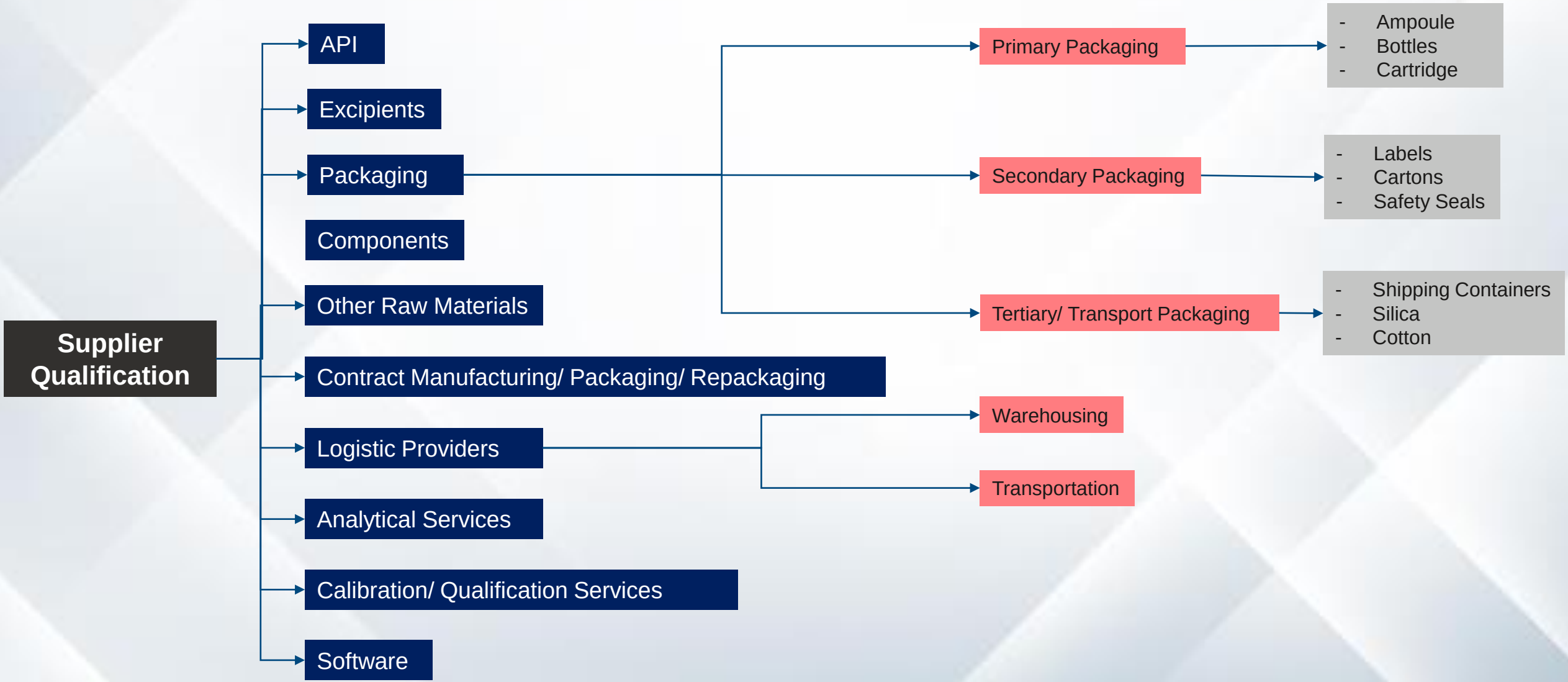

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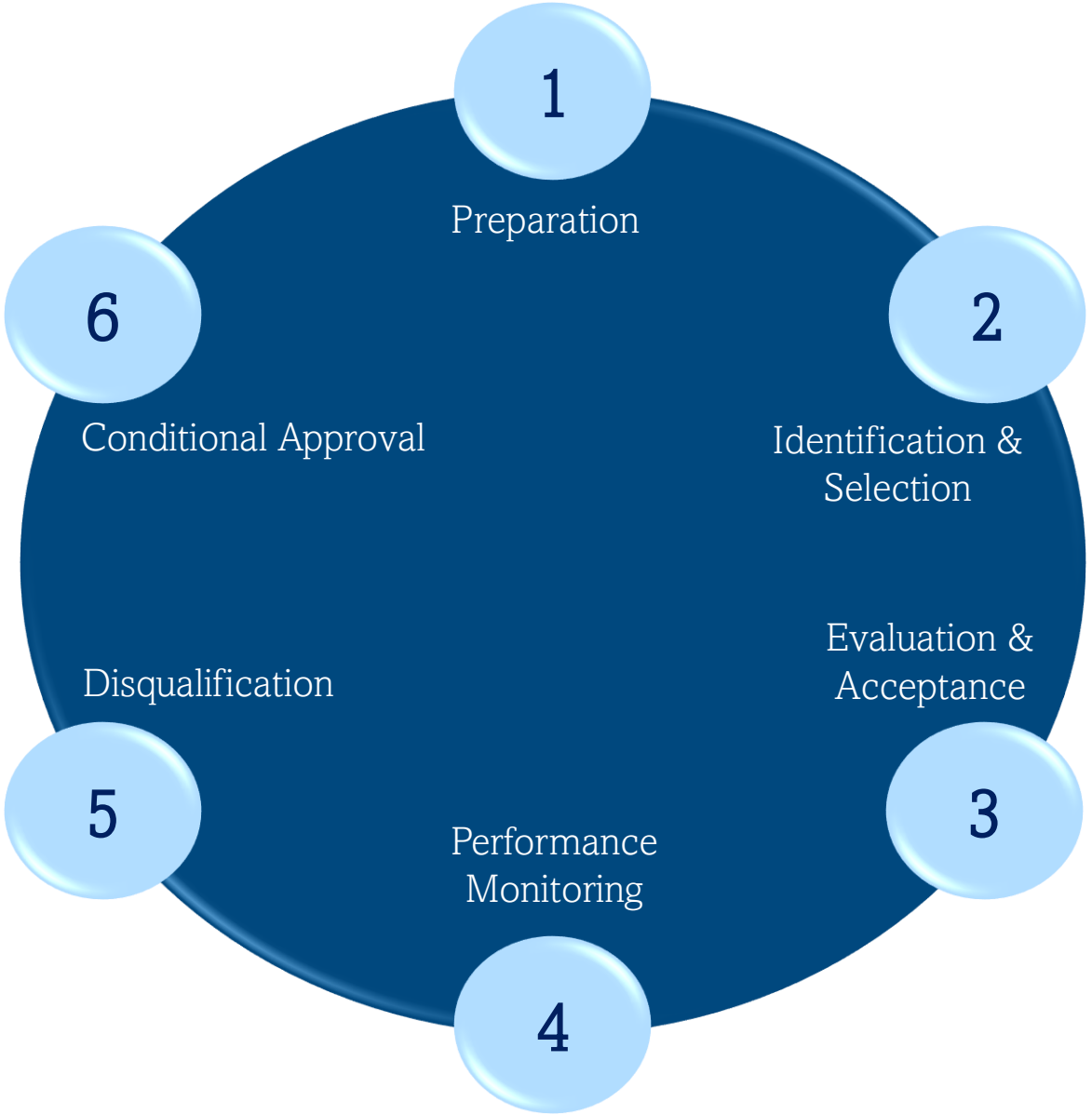
Supplier Qualification Life Cycle

Supplier Qualification Life Cycle: Steps and Tasks



Supplier Qualification Life Cycle: Steps and Tasks

- Nominate a supplier qualification process owner
- Build a cross-functional team
- Identify material and/ or service requirements
- Establish material and service criticality

- ICH Q8: Pharmaceutical Development
- ICH Q9: Quality Risk Management
- ICH Q10: Pharmaceutical Quality System
- ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Supplier Qualification Life Cycle: Steps and Tasks

- Establish supplier requirements
- Identify potential suppliers
- Sign confidentiality/ nondisclosure agreements
- Make a risk assessment
- Select suppliers for evaluation

Risk management

- USP <1079>: Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products
- ICH Q9: Quality Risk Management

Points to be considered when assessing and controlling risks

Risk Category	Points to Consider
Material-related risks	• Use in patient and/ or business critical products (irrespective of material cost) • Degree of use across product lines (irrespective of material cost) • Available inventory (internally and/ or externally) irrespective of material cost • Consider supplier's reject/ discard rate • Consider variability in process capability impacting the final product • Material performance based on information supplied by supply chain intelligence • Financial impact: cost of material and/ or service, cost and time of the alternate source • Product sensitivity ○ Sterility, temperature sensitivity, light sensitivity, etc. • Impact of primary and secondary packaging on material integrity

Capability	• Manufacturing
	  ○ Pharmaceutical: biologic, vaccine, sterile, nonsterile, etc.
	  ○ Device: Class III, Class II, Class I, etc.
	• Service
	  ○ Familiarity with changing regulations in all countries of service
	  ○ Upgrade capabilities
	  ○ Package, delivery, and route qualification and traceability

Stock-out risk to patients	• New product • Orphan product • Availability of alternatives
Financial risk to the business	• High cost of discards, loss of market share, impact to share-holders, etc.
Location/ Supply chain complexity	• Physical distance • Political boundaries and regulations

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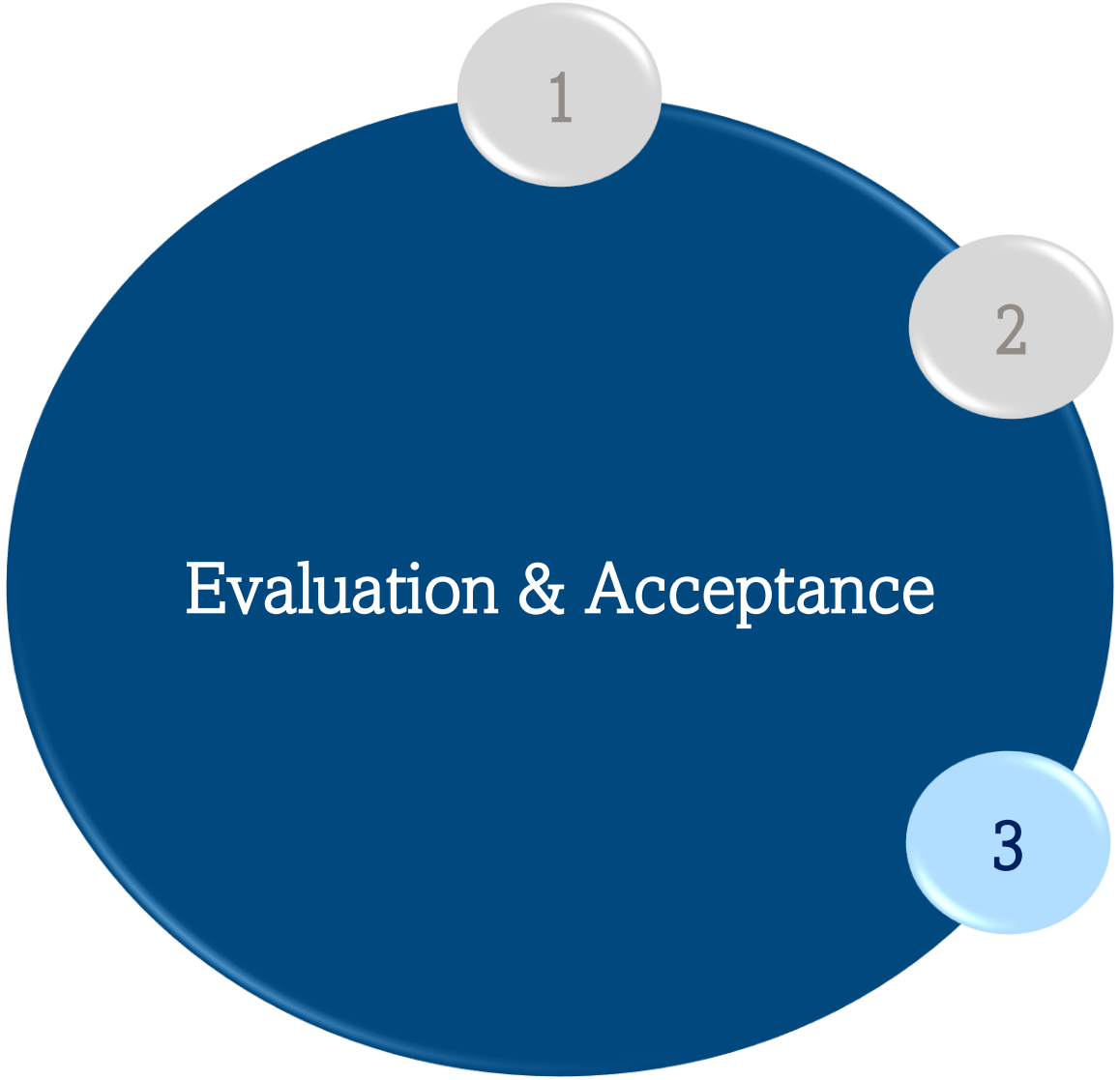
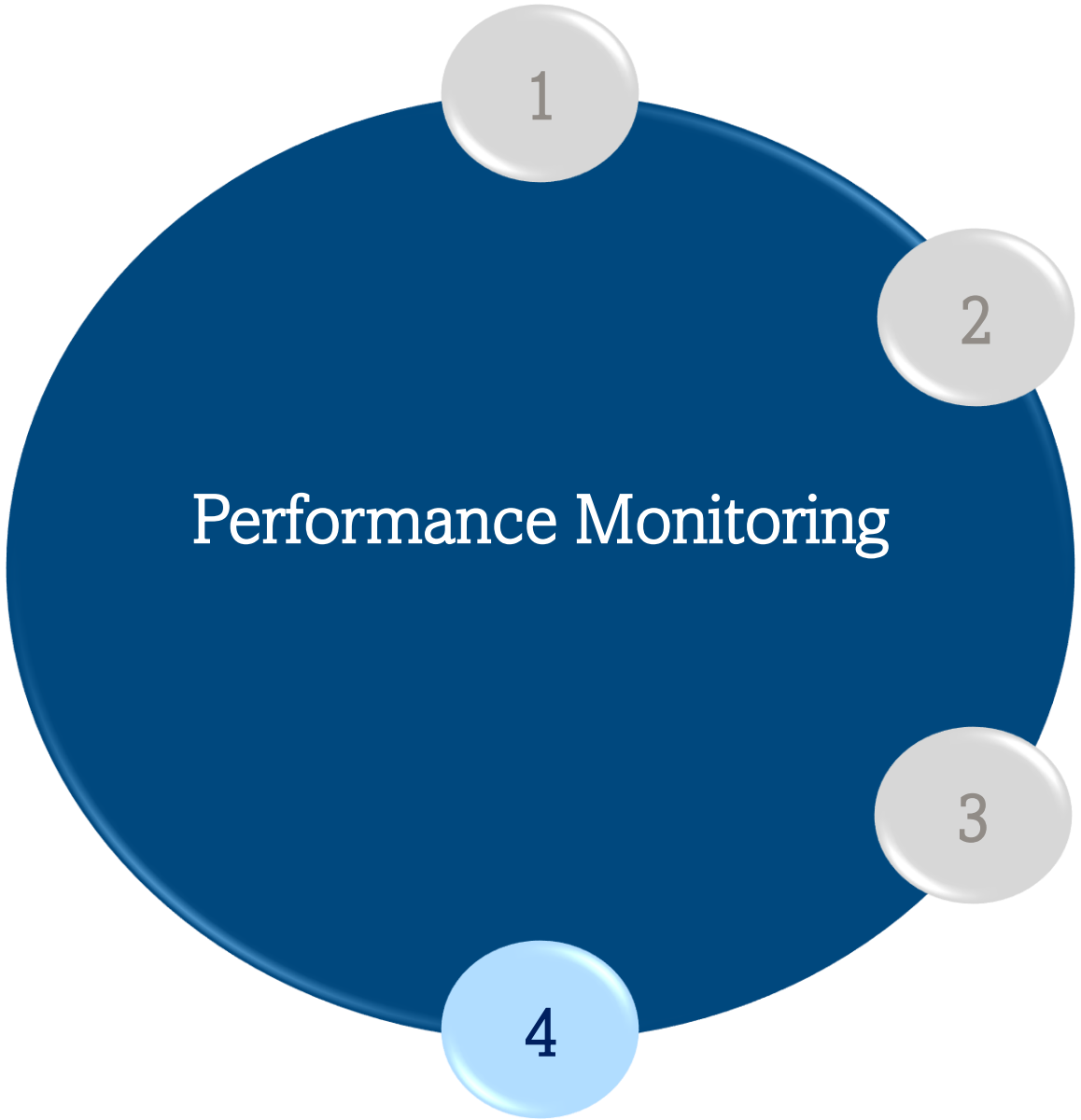
Supplier Qualification Life Cycle: Steps and Tasks



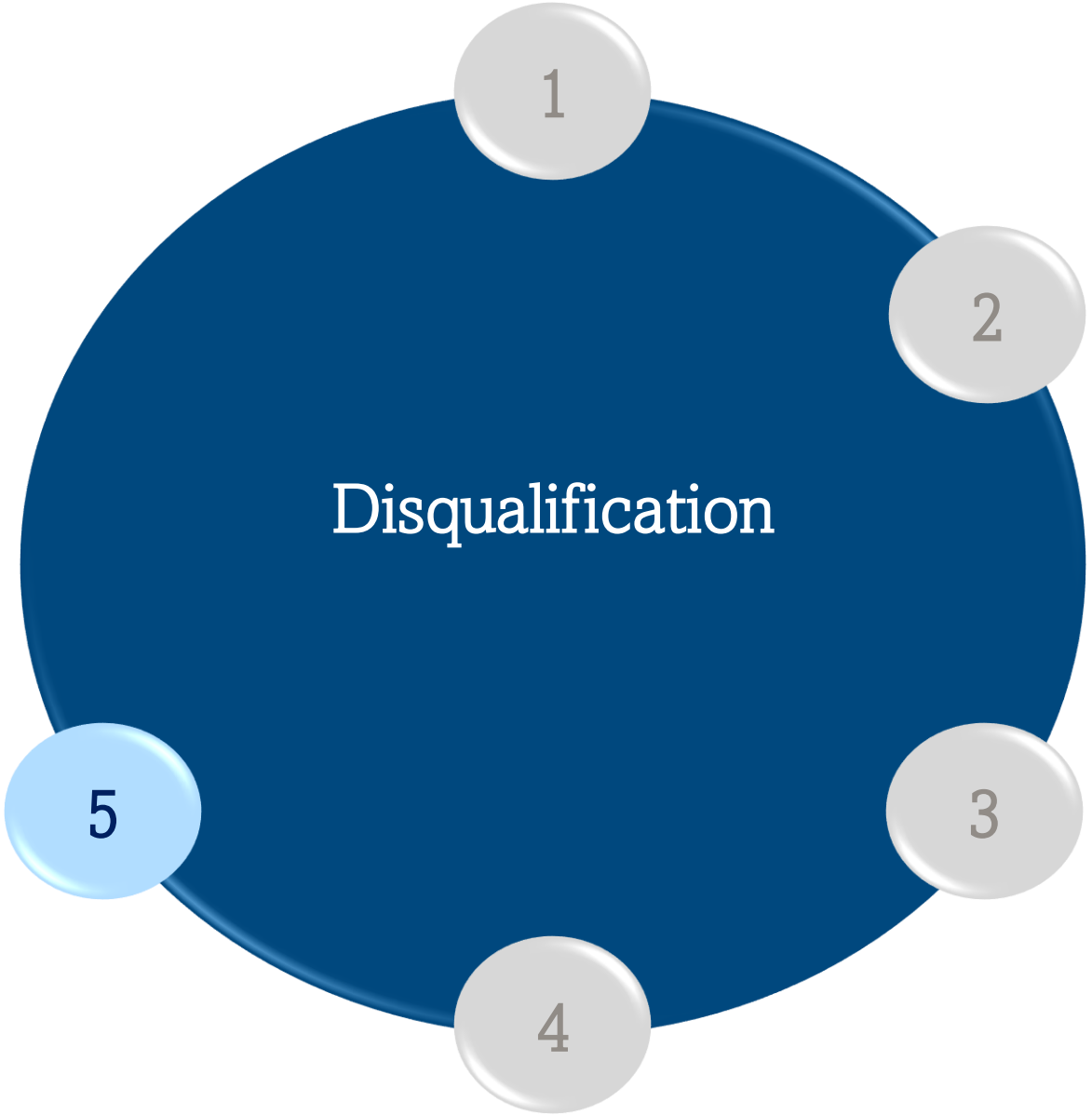
- Perform evaluation based on risk assessment through the following: I) documentation review; II) on-site audits; and III) sample request for analysis
- Build the supplier qualification database

Supplier Qualification Life Cycle: Steps and Tasks



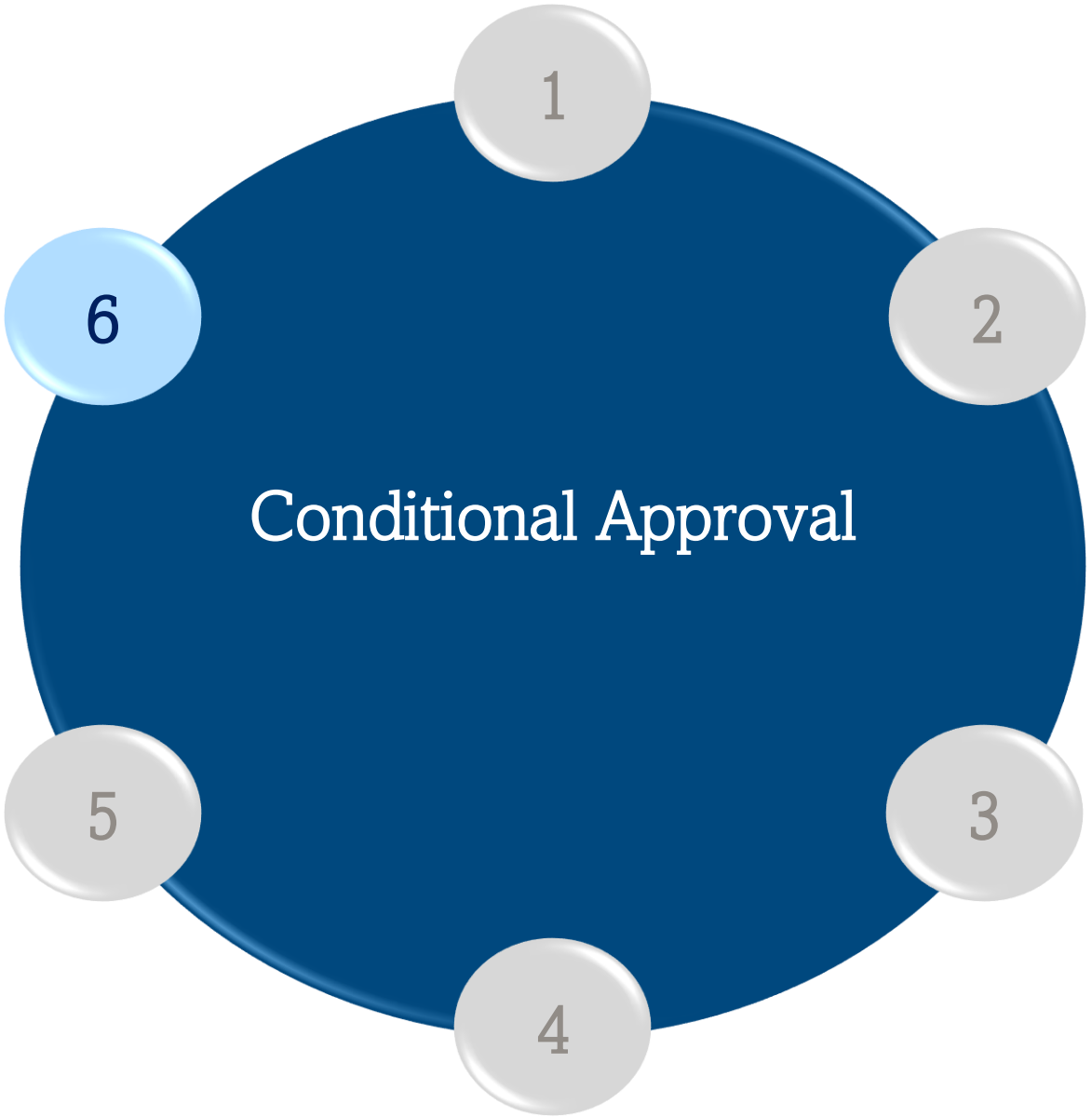
- Establish and agree on key performance indicatiors (KPIs) and monitor the supplier performance against the contract and/ or quality agreement
- Evaluate the supplier performance at regular intervals
- Make decisions based on the evaluation, e.g., ask for correction action and preventive action (CAPA), quality agreement review, contract termination

Supplier Qualification Life Cycle: Steps and Tasks



- Document the circumstances
- Update the supplier database

Supplier Qualification Life Cycle: Steps and Tasks



- Explanation and measures to mitigate the risk

Supplier Qualification
European Guidelines vs FDA Guidelines

European Guidelines		FDA Guidelines
European Medicines Agency (EMA) and national regulatory bodies	Regulatory Authorities	Food and Drug Administration (FDA)
"GMP Supplier Qualification"	Qualification terminology	"Supplier Evaluation" or "Supplier Assessment"
Requires involvement of a QP	Qualified Person (QP)	Does not have an equivalent role
Emphasise a risk-based approach	Risk-based approach	Consider risk, but does not explicitly emphasised it in its regulations

European Guidelines		FDA Guidelines
Emphasise comprehensive documentation to demonstrate Supplier qualification	Documentation requirements	Detailed guidance
Does have MRAs in place	Mutual Recognition Agreements (MRAs)	Does not have similar MRAs in place
Rely on inspections conducted by competent authorities from member states	Inspection practices	Conducts routine inspections of manufacturers and ito their suppliers
Supplier Qualification is governed by European Union guidelines and regulations	Legal framework	21 CFR Part 211

Challenges


QUESTIONS


THANK
YOU