Making the process clearer and more efficient for manufacturers and PQT-VC

Outline

- Summary of Service Codes
- Submission via MedNet
- The process
  - Determination of Pathway
  - Pre-submission Request
  - New Product Submissions
  - Dossier Format – Module Approach
  - New Submissions for Specification
  - Changes

Summary of Service Codes

Service Code	Name	Target Review Time
PQ100	Request For Determination of Pathway	2 months
PQ200	Protocol Review	3 months
PQ300	New Product	12 months
PQ301	New Equivalent Product	12 months
PQ400	New Specification for Source Material (TC/TK or other)	12 months*
PQ401	Extension of Existing Specification for Source Material (TC/TK or other)	12 months*
PQ500	PPQC: Major	7 months*
PQ501	PPQC: Minor	3 months
PQ510	Change to Specification/Production of Source Material (TC/TK or other)	12 months*

* For those actions which include JMPS review, established submission/review schedules should be followed. As such, the target review time may vary.

Calculating Review Time

The review time is calculated based on the number of days the application is under assessment by WHO PQT-VC.

The presented target review times will be reconsidered at such time when fee for service models are considered for PQT-VC

Submission via MedNet

Considerations:

- Ensure files are uploaded to your company's secure space, not the Mednet home page
- Files with special characters in the name (Ex: %, &, +,…) cannot be downloaded
- Utilize the functionality to create and name hierarchical folders to separate products and submissions
- Ensure file names are reflective of the file contents
- PQT-VC does not search Mednet for submissions. You must inform PQT-VC upon finalization of your submission.

The process

- Determination of Pathway
- Pre-submission Request
- New Product Submissions
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Determination of Pathway

PQ100 – Request for Determination of Pathway (RDP)

Description – All new vector control products in development for which the manufacture is interested submitting to WHO for evaluation should submit a request for determination of pathway.

Contents – RDP Form, Cover Letter, and label (if available)

Timeline – 2 months

Purpose:

- Inform applicants of data requirements and relevant WHO review processes
- Determine eligibility for PQ decision making

Considerations

- If a new product application is submitted without having first submitted an RDP, or if there are significant differences between the submitted product and a previously submitted RDP, the determination of pathway process will be completed based on the submission.
- The determination of pathway is based on the product type/use, active ingredient/mode of action, target vector, disease intended to be impacted. The determination is made by the relevant disease program
- One RDP may result in multiple responses depending on varying use/vector/disease combinations
- RDP(s) may be necessary for expanded uses and/or target vectors

Submitted RDPs: Challenges

Broad range of diseases identified – beyond those covered by GMP/NTD

Broad range of vectors/public health pests

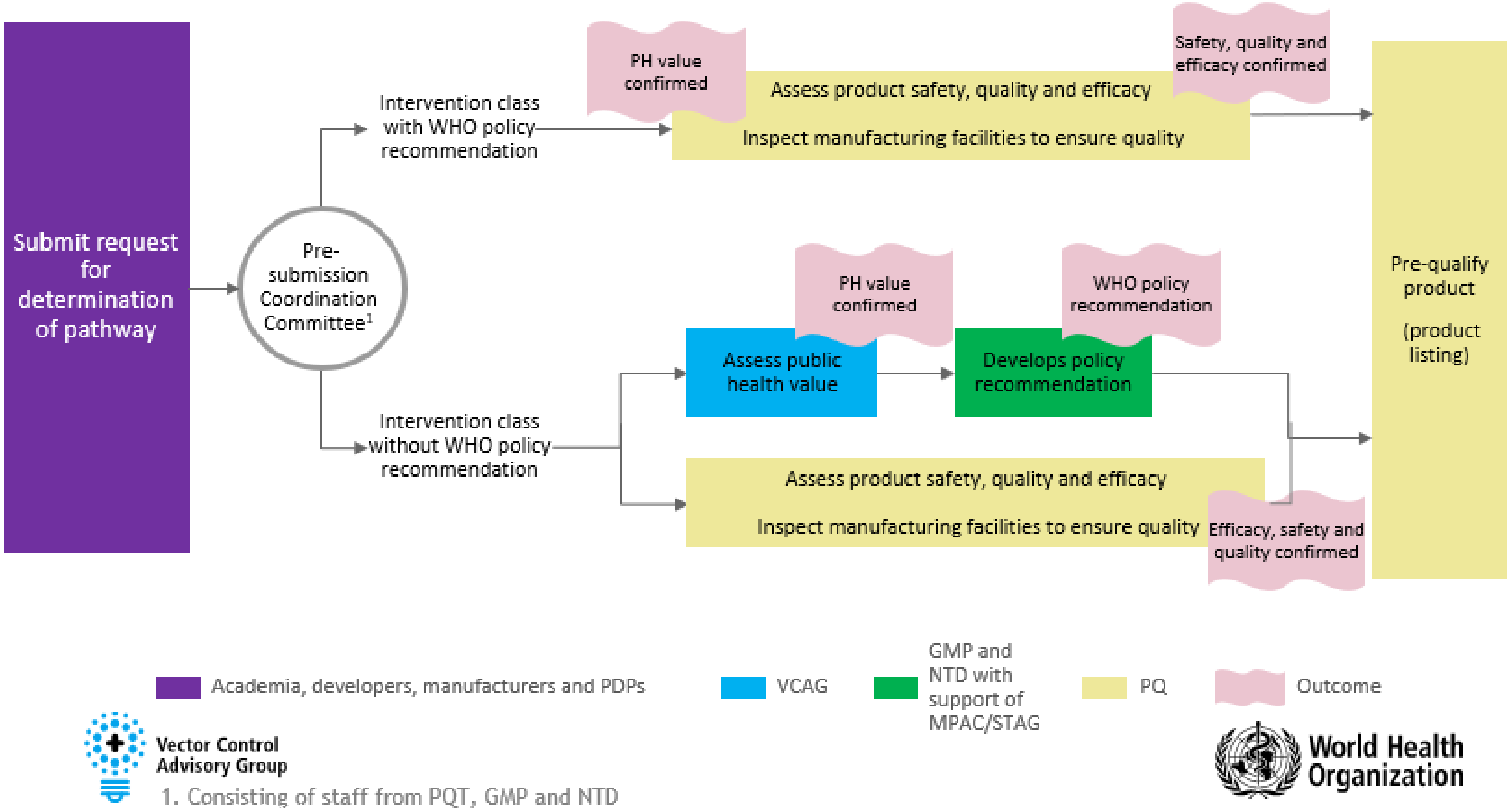
Vector/disease combinations are not always clear

Novel approaches to existing interventions may challenge existing policy recommendation definitions thereby requiring additional time for the respective disease program to respond

Next Steps – Determination of Pathway

WHO is conducting an internal review of the RDP process to determine if changes to the approaches/procedures are needed.

The respective disease programs are continuing the review of existing policy recommendations.

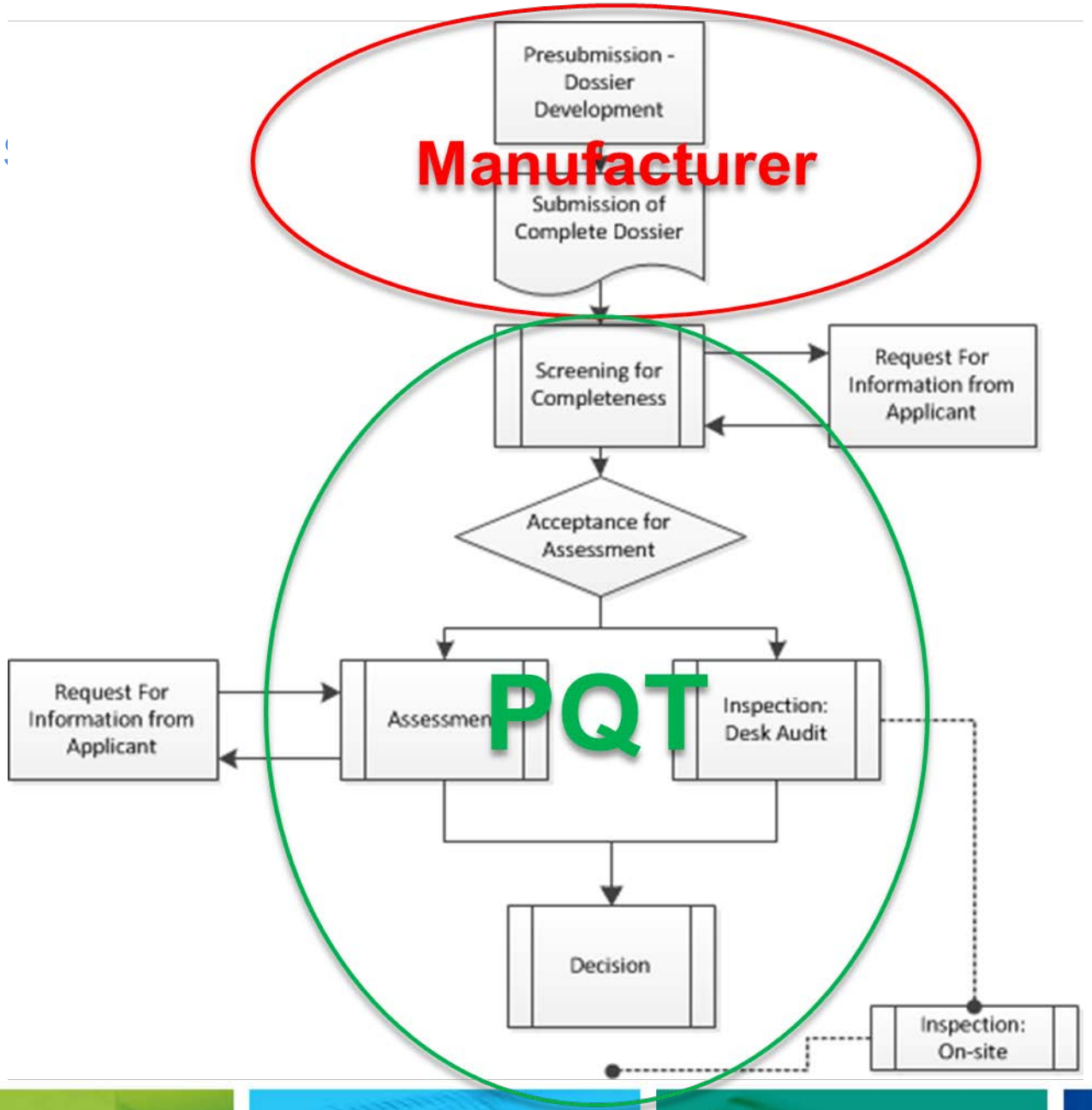


Vector Control Advisory Group

World Health Organization

1. Consisting of staff from PQT, GMP and NTD

Prequalification Proces



Pre-submission Request

PQ200 – Protocol Review

Description - Prior to submitting an application for a new product or change to a listed product, the applicant may submit protocol(s) for review by PQT-VC. PQT-VC does not approve protocol but can provide comments to be considered by the study sponsor/investigator.

Contents –Cover Letter (including list of documents provided), Proposed Protocol(s)

Timeline – 3 months

Considerations:

- The submission of protocol for which studies have already been initiated/completed is not a good use of time/resources
- Protocol designed to investigate public health outcomes through clinical trials are within the purview of VCAG. However, PQT-VC may be requested to review methodologies to investigate entomological outcome within such trials.

Submissions for Prequalification

PQ300 – New Product

Description - This service code is for new products submitted for prequalification.

Contents – Modules 1-6

Timeline – 12 months

Considerations:

- See slides on Modules
- This service code is also applicable for products which are progressing through VCAG. A PQ300 submission can be made at any time; however, a prequalification decision may be dependent on the outcome of the policy recommendation development process for GMP and/or NTD.

PQ301 – New Product claiming Equivalence

Description - This service code is for new products submitted for prequalification which claim equivalence to another prequalified product.

Contents – Modules 1-3, 5, 6

Timeline – 12 months

Considerations:

- The PQT-VC policy for validation of a claim of equivalency is under review

Dossier Format – Module Approach

Advantages to using a Module Approach

- Based on OECD standard dossier format for agricultural pesticide applications
- Easier to submit electronically
- More efficient to screen for completeness
- Easier to provide the data to the appropriate experts
- Contributes to collaboration and standardization

Module 1: Administrative information and labelling

- Cover letter
  - Ensure that the “request” is clearly stated
- Application form
  - Ensure the application form is complete and signed
- Table of Contents
  - Ensure that the file names in the dossier match the titles provided in the Table of Contents
  - If additional information is provided or documents revised, an updated ToC should be provided for the particular action
- Declaration of Labelling
  - Utilize existing guidance
  - Ensure claims are substantiated by supporting information submitted within the dossier

Module 2: Discipline summaries

- Data and manufacturer conclusions are summarized in three documents:
  - Summary of Quality Dossier
  - Summary of Safety Dossier
  - Summary of Efficacy Dossier
- This is the applicant's opportunity to provide a summary of the supporting information provided for each discipline and communicate the applicants interpretation of the supporting information.

Module 3: Quality Dossier

- Physical/Chemical Data
  - Ensure all supporting data is submitted
  - Studies must be submitted in English
  - Ensure studies are finalized and include signatures, including for GLP compliance
- Declaration of Product Formulation
  - The complete formula must be provided
  - Sources of AIs must match those identified on the declaration of manufacturing sites or LOAs provided to verify intermediary distributors
- Description of Manufacturing Process
  - This is not a standardized form
  - Ensure to describe the complete production process including description of chemical reactions (if applicable)
- Declaration of Manufacturing Sites
  - All relevant sites must be identified
  - The information provided on this form will be used to publish the manufacturing sites for the product (upon prequalification)
  - This is a living document which should be updated over time to reflect relevant changes
- Confidential Appendices

Module 4: Safety Dossier

- Active ingredient Specific Hazard Assessment (or summary of publicly available information citing the safety profile)

- Product Risk Assessment (Occupational and Residential Exposure)

- Acute toxicology (6-pack)
  - Acute Inhalation
  - Acute Oral
  - Acute Dermal
  - Primary Eye Irritation
  - Primary Skin Irritation
  - Dermal Sensitization

Module 5: Efficacy Dossier

- Ensure to include raw data for submitted studies in excel format
- Statistical analyses must be fully described
- Analytical chemistry studies conducted to verify identity of product samples used in testing or to validate application rates should be included as a sub folder in Module 5

Decision making process

- Error correction
  - Decision documents are shared with the applicant prior to publication for error correction. This is an opportunity for the applicant to ensure that the decision document is factually correct. It is not an opportunity to comment on the approaches nor conclusions of the assessment

Submissions for Specifications

PQ400 – New Specification for Source Material (TC/TK or other)

Description – This service code is to support the establishment of WHO specifications for source materials of active ingredients or synergists to be used for the formulation of vector control products.

Contents – See FAO/WHO Manual for the development of pesticide specifications, Declaration of Manufacturing Sites

Timeline – 12 months

Considerations:

- The source materials (TC/TK and others) of active ingredients and synergists used for formulating prequalified vector control products must be supported by an evaluation report confirming adherence to established WHO specifications.
- In some cases, the source material may be a formulation (ex. SC). In this case, the source must be supported by a evaluation report and the applicant must provide verification that the preceding TC/TK is also supported by an evaluation report.

PQ401 – Extension of Existing Specification for Source Material (TC/TK or other)

Description - This service code is for the submission of applications requesting assessment of the production of source materials of active ingredients or synergists to be used for the formulation of vector control products to demonstrate accordance with existing WHO specifications.

Contents – See FAO/WHO Manual for the development of pesticide specifications, Declaration of Manufacturing Sites

Timeline – 12 months

Considerations:

- In the event that a reference specification changes, manufacturers may be required to submit additional information for the continued extension of the specification

Change Submissions – PQ Products and/or Specifications

PQ500 – PPQC: Major

Description - An applicant may submit a variation application to amend a prequalified product or active ingredient manufacturing site. This service code is for any change request which requires the review of data.

Contents – Module 1, Modules 2-6 as needed depending on change

Timeline – 7 months*

PQ501 – PPQC: Minor

Description - An applicant may submit a change application to amend a prequalified product or active ingredient manufacturing site. This service code is for any change request which does not require the review of data.

Contents – Module 1, Modules 2-6 as needed depending on change

Timeline – 3 months

PQ510 – Change to Specification/Production of Source Material (TC/TK or other)

Description - An applicant may submit a change application to amend a specification or evaluation report supporting a WHO evaluated source materials (TC/TK or other).

Contents - See FAO/WHO Manual for the development of pesticide specifications, Declaration of Manufacturing Sites

Timeline – 12 Months*

Common Change Request – Adding a Manufacturing Site

PPQC 500 (Major) or PPQC 501 (Minor)?

- What is the function of the site?
- Is the process the same?
- Is the SMF/QMS the same?
- Does the data on file support the production/function of the new site?
- Is validation data needed? Ex. 5 batch analysis?