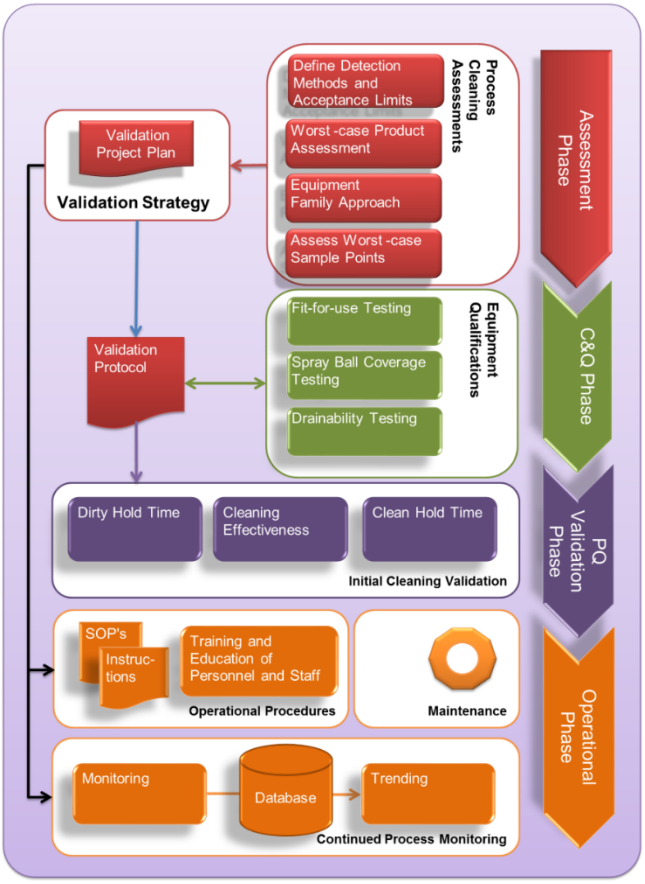
CLEANING VALIDATION FACTSHEET

Why…..?

Regulators, companies and customers in the pharmaceutical manufacturing industry remain highly focused on Cleaning Validation.
Virtually every pharmaceutical or biopharma company we work with is interested in a compliant, pragmatic and risk based Cleaning Validation approach.

Progress-PME believes that integrating Cleaning Validation in an effective Quality System supported by Quality Risk Management assures that:

- ✓ Operational cleaning efforts are balanced with (Cleaning Validation related) risks to patients.
- ✓ Operational cleaning processes and their risk related attributes are understood, assessed for impact, validated and mitigated as required.



Cleaning Validation Life Cycle Management

Face the challenge….!

Compliance to Cleaning Validation is complex and certainly not a *'copy –paste'* exercise.
Compliance requires knowledge of laws, regulations, guidelines, progressive regulatory expectations and the latest industry practices.

No two companies, products or manufacturing processes are alike; therefore Cleaning Validation Life Cycle management is to a great extent a matter of customization.
We support effective Cleaning Validation based on pragmatic risk management, with respect to all required Cleaning Validation attributes.

Current state assessments

Effective Cleaning Validation Management should include all stakeholders.
Progress-PME has the knowledge and expertise to assess the current state of your business and can support you in the following areas:

- ✓ A sound company policy that reflects regulatory expectations, pragmatic approaches and proper tie-ins with other Quality Management Systems.
- ✓ Risk based models (toolkits) to define and uniformize Cleaning Validation documents, strategies and proper acceptance criteria.
- ✓ Validation expertise to create, execute and finalize Cleaning Validation documentation.
- ✓ Cleaning Validation Life Cycle management through proper maintenance and monitoring.
- ✓ QC: with proper analytical methods, training, sample handling and sample flows.
- ✓ Operations: with properly trained personnel, workable cleaning procedures and cleanable processes (Quality by Design).
- ✓ QA: enabled to understand and assure Cleaning Validation requirements and critical attributes.

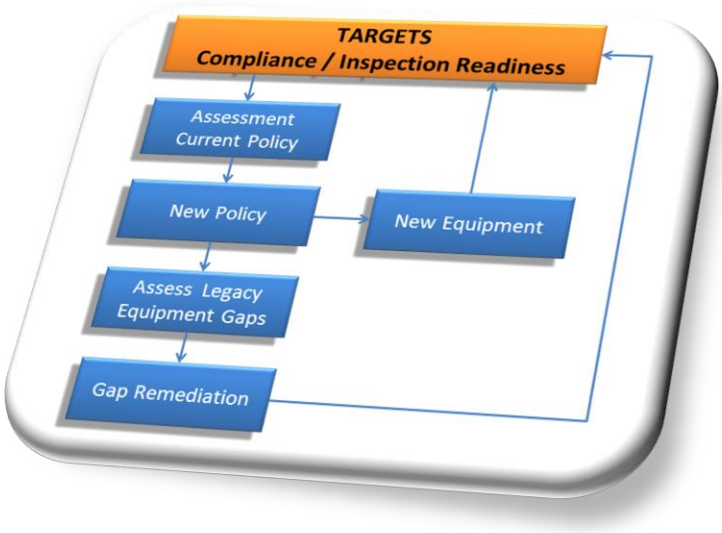
PROGRESS
project management & engineering

CLEANING VALIDATION FACTSHEET

Progress-PME improvement model

Progress-PME has gained wide experience in Cleaning Validation with several successful improvement projects.

We have assessed the current state of Cleaning Validation management and implemented successful, evidence-based improvements for multiple pharmaceutical clients.



How can we help….?

We can support you on both strategic and tactical levels:

- ✓ Strategic assessments and consulting.
- ✓ Development of '*fit for purpose*' Cleaning Validation Life Cycle policy and management.
- ✓ Top-to-bottom implementation of Cleaning Validation quality attributes from strategic (policy) level to tactical (operator) level. We can provide guidance to facilitate a behavioral change approach if necessary.
- ✓ Executing a complete Process Cleaning Validation from start to finish.
- ✓ Leading or supporting Root Cause Investigations related to Cleaning Validation deviations.
- ✓ Providing solutions for complex and unique Cleaning Validation situations.
- ✓ Set-up of Process Cleaning verification strategies for start-up companies (clinical phase).
- ✓ Development of a 'toolkit' to support Cleaning Validation teams.

Toolkit solutions

We can develop a customized 'toolkit' that provides effective solutions and guidance to in-depth Cleaning Validation issues, for instance:

- ✓ How to define your worst-case product and how to benefit from a matrix approach.
- ✓ How to define a family approach for equipment.
- ✓ How to define worst-case sample points and how to define sample strategies.
- ✓ How to investigate the loss on swab recovery to allow proper corrections of QC results.
- ✓ How to reduce false positive sampling results by instructions on good sampling techniques for rinse water and (TOC) swab sampling.
- ✓ How to incorporate a reliable process cleaning monitoring program during the operational phase of the process life cycle.

Track record and facts

To give a brief selection of our Cleaning Validation experience, we have:

- ✓ Supported generic, pharmaceutical and biopharmaceutical (biotech) industries.
- ✓ Successfully performed top-to-bottom Cleaning Validation 'makeovers' at multiple small and large (bio)pharmaceutical companies in The Netherlands and Belgium. Subsequent FDA inspections yielded no observations related to Cleaning Validation.
- ✓ Supported over 10 clients with various Cleaning Validation activities (e.g. writing, executing and reporting validation studies).
- ✓ Organized several joint venture seminars as a Centre of Expertise on Cleaning Validation topics.

Who are we….?

Progress-PME is an independent Project Management and Consultancy Company with customers in life science, (bio)pharmaceutical, medical device and healthcare industries.

The company was founded in 1999, operates internationally and provides support throughout the entire range of process development to commercial production.

Progress-PME provide services in the field of project and interim management and Consultancy.

Fields of expertise: CMC, Quality (cGxP), Validation, Engineering, LEAN Six Sigma.