METTLER TOLEDO Validation

What does IQ mean to you?

What do you associate with DQ, OQ and PQ?

If you automatically associated these acronyms with production system validation, congratulations; no need for you to read on. If, however, you related IQ to intelligence and were unable to place the remaining acronyms in a specific context, please take a few minutes to continue reading – it will pay off.



What is validation?

Application software

System software

Hardware

Computer system

By validation of a computerized system we mean a documented verification that a specific computerized system performs according to its specifications. Or, in short: A system does what it is expected to do, and this performance can be documented.

Computerized system

Whose systems ought to be validated?

Operating procedures

Equipment

Controlled process

Manufacturers employing GMP critical processes are required to maintain validated systems. In addition to pharmaceutical companies, food and cosmetics manufacturers find themselves increasingly confronted with this new challenge.

Benefits of validation

- Compliance with regulatory requirements
- Minimized risk of malfunction
- Reduction in cost of continuous operation
- Increased knowledge of processes through improved system knowledge
- Greater trust in computerized system

Please turn over for an explanation of the terms DQ, IQ, OQ and PQ, and learn how METTLER TOLEDO can assist you in validating your computerized system.



Life cycle of a computerized system

Requirements ···· specification Performance qualification

Functional specifications

Operational qualification

Design specifications Installation qualification

Implementation

System Validation – A Helping Hand to Maintain Product and Process Quality

Check out METTLER TOLEDO's support in these phases of your validation procedures:

Design Qualification (DQ)

Documented verification that a computerized system has been developed according to its specifications.

Installation Qualification (IQ)

Documented verification that a computerized system has been executed according to its design specifications (DQ)

Operational Qualification (OQ)

Documented verification that a computerized system performs as expected, meeting its specifications.

Performance Qualification (PQ)

Documented verification that a computerized system performs as expected, meeting its specifications even under strain in the intended operating ranges.

METTLER TOLEDO Services	Design Qualification (DQ)	Installation Qualification (IQ)	Operational Qualification (OQ)	Performance Qualification (PQ)	Maintenance Qualification (MQ)
Documentation for standard software					
Documentation for validation					
Standard software services					
Validation services					

 The following manufacturers are familiar with our validation services.
 Alza Pharmaceuticals, USA

 Mathematical miliar with our validation services.
 Asta Medica, Germany

 Please contact us to find out more about the specific benefits for you.
 Boots, UK

 Dey Labs, USA
 Carentech USA

Asta Medica, Germany Astra Avcus, Sweden Boots, UK Dev Labs, USA Genentech, USA Holopack International, USA Knoll, Germany Merck Mexico de C.V., Mexico Oranienburger Pharmawerk, Germany Organon, USA Pfizer Animal Health, Canada Pfizer Ilaçlari, Turkey Pharmacia & Upjohn, Sweden Roche, Switzerland Roxanne Laboratories, USA Wasserburger Arzneimittelwerk, Germany Contact address:

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