Validatie autoclaaf

TOM KERKHOFS, BUSINESS DEVELOPMENT LIFE SCIENCES

Validatie?

- ISO 17665

3.60
validation
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification

- EN 285

Spreekt enkel van software validatie, geen procesvalidatie. Vermeldt wel enkel parameters, die gebruikt kunnen worden als validatie-criteria.

- D6103b

Validatie
Geprotocolleerde opeenvolging van werkwijzen voor het verkrijgen, vastleggen en interpreteren van resultaten, die nodig zijn om vast te stellen dat een procedure constant hetzelfde product levert, in overeenstemming met van tevoren vast ingestelde specificaties.

Validatie?

- Validatie of kwalificatie?

Qualification is documented evidence that a specific equipment, facility or system is fit/ready for intended use.
Validation is documenting that the way equipment, facility or system used will result in product meeting its predetermined specifications and quality attributes.

***Things are qualified**: equipment, systems etc.*
***Process/Procedures** (the way we use things) **are validated**.*

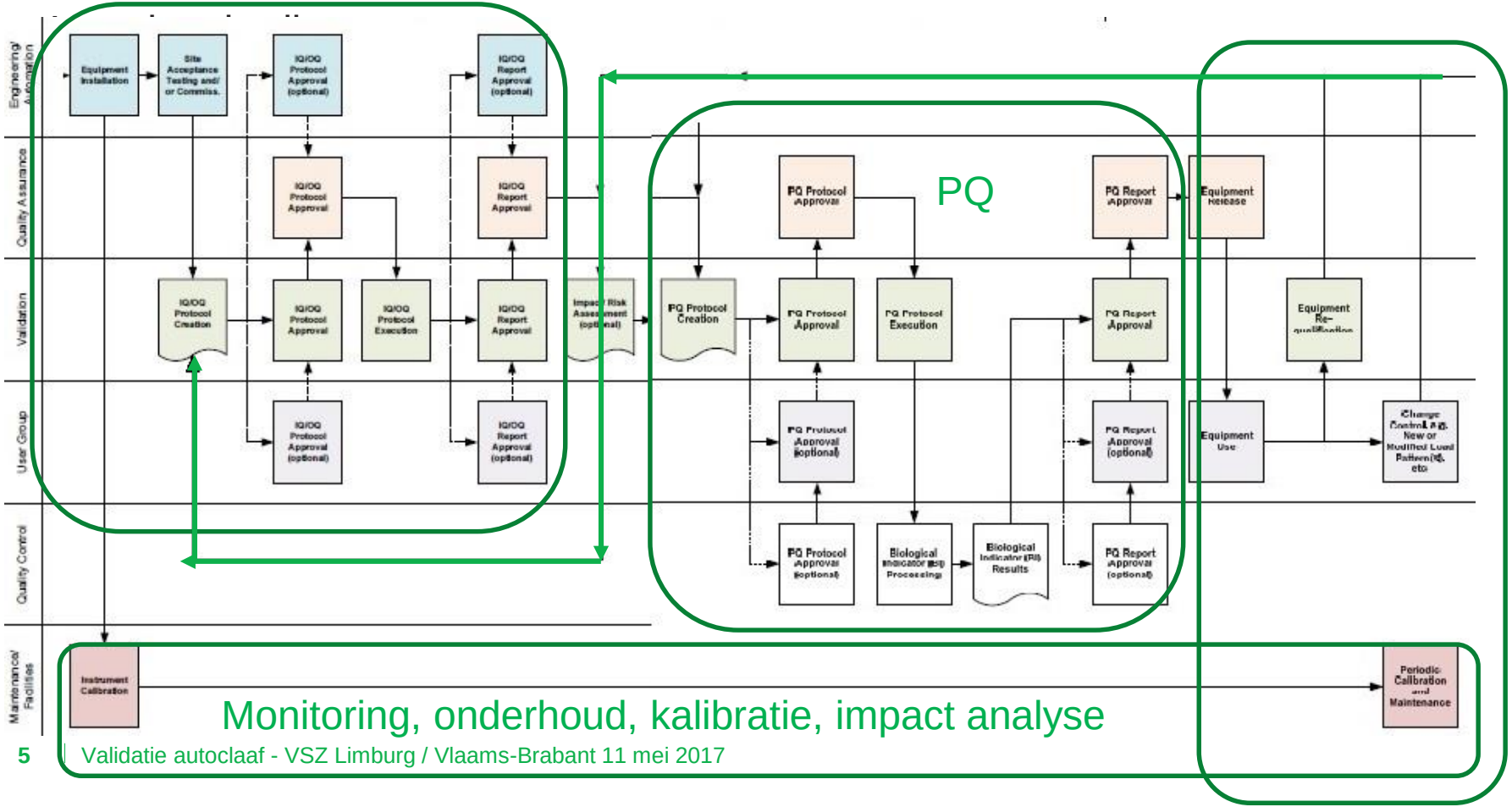
=> ***Validatie autoclaaf volgens eigenlijk gebruik***

Validatie?

- Voor ingebruikname
  - Installatie kwalificatie
  - Operationele kwalificatie
  - Performance kwalificatie
- Tijdens gebruik
  - Periodiek onderhoud (inclusief **kalibratie**)
  - Monitoring (controle uitprint / indicatoren / …)
  - Logbook van incidenten
  - Hervalidatie
- Na gebruik
  - Decommissioning (uitdienstvalidatie)

Validatie?

IQ/OQ



ISO 17665 - general

9 Validation

9.1 General

9.1.1 Each stage of validation shall be carried out in accordance with a documented procedure.

9.1.2 It shall be verified that each item of fixed and portable equipment used during validation complies with its specification.

9.1.3 Any modifications to product, equipment, or sterilization process carried out during validation shall be recorded and justified, and the specification(s) changed accordingly (see also 12).

9.1.4 The measuring chain for each test instrument used for validation shall have:

— calibration traceable to a national standard;

— a valid maintenance certificate (if appropriate);

— a calibration status verified according to the technical and applicable management requirements;

— verification of calibration carried out at a value(s) used to control the sterilization process and judge the results of the test in which the measuring chain is used.

Validatieprotocol met onderbouwing van testaanpak + gebruikt materiaal

ISO 17665 - general

9.1.5 The correlation between readings indicated and recorded by instruments fitted to the sterilizer and readings registered by independent test instruments having sensors in similar locations shall be verified.

9.1.6 It shall be verified during installation qualification (IQ), operational qualification (OQ) or performance qualification (PQ), as applicable, that fault recognition systems function and comply with their performance specifications.

9.1.7 If an existing sterilizer and sterilization process is to be used to process a new product, the IQ and OQ stages of validation may be omitted, provided that changes are not made to the equipment or to existing sterilizer load(s) that could affect delivery of the existing sterilization process.

9.1.8 The validity of the proposed periodic test(s) shall be verified [see 6.1.1 l) and 10.3].

Validatie adhv normale beladingswijze,
indicatoren + procedures
ziekenhuizen

ISO 17665 – Installation Qualification

9.2 Installation qualification (IQ)

9.2.1 Equipment

It shall be verified that the equipment and documentation comply with 6.2.1, 6.2.2 and 6.2.3 and that services comply with 6.2.3.

Volledige IQ + alarmtesten conform D6103b

9.2.2 Installation

It shall be verified that the installation complies with 6.2.3.

9.2.3 Function

It shall be verified that the equipment and operational safety systems detailed in 6.2.1 function in accordance with their specifications, the operating cycle(s) is in accordance with 6.1.1 a), and that there is no evidence of leakage from the services or the equipment.

ISO 17665 - general

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9.1.7 If an existing sterilizer and sterilization process is to be used to process a new product, the IQ and OQ stages of validation may be omitted, provided that changes are not made to the equipment or to existing sterilizer load(s) that could affect delivery of the existing sterilization process.

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Validatie adhv normale beladingswijze,
indicatoren + procedures
ziekenhuizen

ISO 17665 – Operational Qualification

Agidens

9.3 Operational qualification (OQ)

9.3.1 Operational qualification shall demonstrate that installed equipment will deliver the sterilization process defined in 8, and shall establish data for each requirement (if applicable) listed in 6.1.

9.3.2 The rationale for the number and locations of the temperature sensors used to demonstrate that requirements are met for temperature distribution in an empty sterilizer chamber (including fixed chamber parts), and also with a test load (if used), shall be documented.

Vermeld in validatieprotocol:

- Oplijsting kritieke programmaparameters per fase
- Locaties afhankelijk van volume autoclaaf (cfr D6103b)
- Verder onder OQ:
  - Lektest
  - Bowie Dick
  - Lege kamer studie (of minimaal beladen)

ISO 17665 – Performance Qualification

Agidens

9.4 Performance qualification (PQ)

9.4.1 Performance qualification shall demonstrate that product has been exposed to the specified sterilization process by the equipment to be used for routine sterilization.

9.4.2 Rationale shall be documented for the number and locations of temperature sensors used to demonstrate that requirements are met in the sterilization load.

Relevante lading per programma!
Worst case lading!

9.4.3 Checks shall include and verify that:

a) documentation confirms successful IQ and OQ;

b) the test sterilization load comprises product that will be routinely processed and that is assigned to a product family(ies) compatible with the one(s) assigned to the sterilization process or that represents the product families presenting the greatest challenge to the sterilization process;

c) the packaging system is identical to that intended for routine production or reprocessing;

d) pre-conditioning is compliant with 6.1.1 d);

e) the load configuration complies with 6.1.1 j) and is known to be the most difficult to sterilize;

f) the size and/or mass of the sterilization load comply with 6.1.1 k).

Luchtverwijdering volgens Bowie Dick:

- Setpunten pulsen
- Op- en afbouw druk tijdens pulsen

ISO 17665 – Performance Qualification

- Relevante lading per programma
  - Bvb geen containers in programma op 121 °C
  - Ladingsconfiguratie volgens werkwijze ziekenhuis

- Worst case lading
  - Als programma op 121 °C, wegens te weinig beschikbare lading, altijd gevuld wordt met andere sets, wordt dit ook gedaan tijdens validatie
  - Worst case lading in overleg met csa-verantwoordelijke
    - Laminaat
    - Holle lading
    - Containers
    - Plastic
    - …

ISO 17665 – Performance Qualification

9.4.4 For each of the following, studies shall establish;

a) conformity to the sterilization process identified in Clause 8 and the limiting process values identified in 7.6;

b) data as required in 6.1.3, if applicable;

c) the exposure profile(s) on and throughout product located in the position(s) identified in 6.1.1 e), 6.1.1 m) and 6.1.1 n);

d) the holding time and the minimum and maximum temperatures and their locations, measured during this time in the sterilization load for processes identified in 6.1.2;

e) the temperature profiles during the plateau period of the sterilization processes identified in 6.1.2 a):

— measured at the reference measuring point;

— measured on or within the sterilization load;

— determined from the sterilizer chamber pressure;

Controle parameters cfr instellingen (bvb holding time)

Theoretische stoomtemperatuur

NOTE Attention is drawn to national or regional requirements when defining the maximum permissible difference between measured and calculated temperatures. See, for example, EN 285.

f) the response of chemical indicators, when used (see 8.8);

ISO 17665 – Performance Qualification

9.4.5 If, in addition to the measurement of physical parameters, the sterilization process is to be based on bioburden, or verified by microbiological methods, biological indicators (see 8.5 or 8.6) shall be positioned in and/or on the product in locations identified in 9.4.4, and then exposed to one of the following:

— a treatment that is reduced relative to that in the sterilization process; the outcome of this treatment is extrapolated to demonstrate that, on application of the sterilization process, the specified requirements for minimum microbicidal effectiveness are met;

— the full extent of the treatment at the lower tolerances of the sterilization process parameters, the outcome of this treatment is used to confirm a prediction that, on the application of the sterilization process, the specified requirements for minimum microbicidal effectiveness are met; or

— an "overkill" process.

NOTE See Annexes B, C and D.

Initiële validatie = 3 x performance qualification per sterilisatieprogramma

9.4.6 PQ shall include a series of at least three consecutive exposures of the sterilization load to the sterilization process, which demonstrate compliance with the sterilization process specification and the reproducibility of the sterilization process.

9.4.7 Non-compliance with the sterilization process specification during PQ shall be reviewed and corrected.

impactanalyse

ISO 17665 – Review

9.5 Review and approval of validation

9.5.1 Information gathered or produced during IQ, OQ and PQ shall be reviewed for conformity to the acceptance criteria specified for each stage of the validation process. The outcome of this review shall be documented and approved (see 4.1.2).

9.5.2 A sterilization process specification, including the process parameters and their tolerances, shall be confirmed. This specification shall include the criteria for designating the sterilization process used for a particular sterilizer load as conforming, and shall document at least the following:

a) the product family(ies) that can be processed;

b) the load configuration(s);

c) the size of the sterilization load and/or its mass;

d) the procedures for any pre-conditioning of product;

e) a description of the packaging system and methods;

f) the distribution of medical devices within a package containing multiple medical devices, if applicable;

g) the periodic tests (see 10.3);

h) the process challenge device and the product family(ies) for which it is relevant;

i) the bioburden, if applicable.

Goedkeuring door interne review + door klant (rapportbespreking)

ISO 17665 – Monitoring

Agidens

10 Routine monitoring and control

10.1 Routine monitoring and control shall be performed on each operating cycle.

Print-out

10.2 Evidence of successful maintenance and requalification (if applicable) shall be verified.

Logboek

10.3 The operational status of the equipment (if applicable) shall be verified by evidence from periodic tests of factors such as (but not limited to) the following:

a) air leakage into the sterilizer chamber;

b) quality of saturated steam or heat transfer media admitted to the sterilizer chamber (which may include checks for non-condensable gas, conductivity of feed water, contaminant(s), moisture content);

stoomtesten

c) automatic control (e.g., a test to verify that the operating cycle continues to function correctly);

d) steam penetration;

e) sterilization process (e.g., a test to verify that the sterilization process remains reproducible).

10.4 Delivery of the sterilization process shall be verified from the results of chemical indicators (see 8.8) or biological indicator systems (see 8.5 or 8.6), if used, and by confirming that within specified tolerances, recorded data from routine monitoring match data from validation.

ISO 17665 – Monitoring

10.5 For saturated steam processes, the data shall include (if applicable):

a) sterilization temperature, chamber pressure and theoretical steam temperature during the plateau period;

b) duration of the plateau period;

c) the chamber temperature and the chamber pressure for at least each stage of the operating cycle;

d) the results obtained from a process challenge device;

e) temperatures and/or pressures in a process monitoring system, if used as part of process control.

10.6 For contained product processes, the data shall include (if applicable):

a) the temperature(s) measured in the reference challenge device, if used as part of process control;

b) the chamber temperature and the chamber pressure profiles for heating, exposure and cooling;

c) the temperature profiles for heating, exposure and cooling in product located in positions identified in 9.4.4 c), if used as part of process control;

d) the plateau period or holding time;

e) the value(s) for the process parameter(s) for homogeneity of the heating media in the sterilizer chamber;

f) results of inspection of the sterilization load to confirm dryness and integrity of the packaging system.

10.7 All records shall be retained in accordance with 4.1.2.

Print-out

ISO 17665 – Vrijgave

11 Product release from sterilization

11.1 Procedures for the review of records and product release from the sterilization process shall be specified. The procedure(s) shall define the requirements (see 9.5.2 and 10.3 as appropriate) for designating a sterilization process as conforming. If a requirement is not met, product shall be designated as non-conforming and handled in accordance with 4.4.

11.2 A system shall be specified to ensure that processed and non-processed items are clearly differentiated.

ISO 17665 – Procescontrole

12 Maintaining process effectiveness

12.1 Demonstration of continued effectiveness

12.1.1 Product presented for sterilization shall comply with

a) the product definition in Clause 7;

b) the load configuration as defined in 6.1.1 j);

c) the size and mass criteria defined in 6.1.1 k).

12.1.2 Successful completion of periodic tests, calibrations, maintenance tasks and requalification carried out at specified intervals shall be verified.

12.1.3 The quality of the environment in which the product is prepared and/or packaged shall be periodically verified.

12.1.4 Requirements for the health, cleanliness and clothing of personnel in the manufacturing and/or packaging area shall be specified and enforced.

12.1.5 If the sterilization process makes use of a vacuum, an air leakage test shall be carried out at specified intervals.

12.1.6 If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam into the sterilizer load, a steam penetration test shall be carried out each day before the sterilizer is used.

The steam penetration test is carried out using a device having a defined challenge to air removal and steam penetration for the process. For industrial applications, if the saturated steam process uses consistent, defined sterilization loads known not to inhibit the penetration of steam, alternative methods may be used based on specified physical measurements and a risk assessment of the likelihood of process failure.

12.1.7 Product shall conform to bioburden requirements, if applicable.

ISO 17665 – Procescontrole

12.2 Recalibration

The accuracy and reliability of each measuring chain used to control, indicate, or record the sterilization process shall be verified periodically in accordance with 4.3.3.

12.3 Maintenance of equipment

12.3.1 Preventative maintenance shall be planned and performed in accordance with documented procedures.

12.3.2 Equipment shall not be used to process product until all specified maintenance tasks have been satisfactorily completed and recorded.

12.3.3 The maintenance plan, maintenance procedures and maintenance records shall be retained (see 4.1.2) and reviewed at specified intervals by a designated person. The results of the review shall be documented.

12.4 Requalification

12.4.1 Requalification of a sterilization process shall be carried out for defined product and specified equipment, at defined intervals and after the assessment of any change (see 12.5). The extent to which requalification is carried out shall be justified.

12.4.2 Requalification procedures shall be specified and records of requalification retained (see 4.1.2).

12.4.3 Requalification data shall be reviewed against specified acceptance criteria in accordance with documented procedures. Records shall be retained (see 4.1.2) of reviews of requalification data together with corrections made and corrective action taken.

Hervalidatie:
Per sterilisatieprogramma 1 x minimaal + 1 x 100 % beladen kamer

Mits geen procesbeïnvloedende parameters veranderd (gecontroleerd ten opzichte van eerdere validatie).

- Luchtverwijderingsfase
- Stoominstallatie
- Vacuümpomp
- Ernstige storing
- …

ISO 17665 – Procescontrole

12.5 Assessment of change

Any change shall be assessed for its impact on the effectiveness of the sterilization process. Changes to be considered (if applicable) shall include:

a) replacement of a part which could cause a process parameter to change;

b) replacement of a part which could cause an increase in leakage into the sterilizer chamber;

c) variation of homogeneity in the sterilizer chamber;

d) new or modified software and/or hardware;

e) any change to a process parameter;

f) any change to services and the outcome of maintenance on a service;

g) any change of packaging and/or packaging procedure;

h) any change of load configuration;

i) any change of product materials, source of materials or design.

The outcome of this assessment, including the rationale for the decisions reached and the extent of changes made to the sterilization process, product or requalification requirements (if applicable), shall be documented.

Validatie?

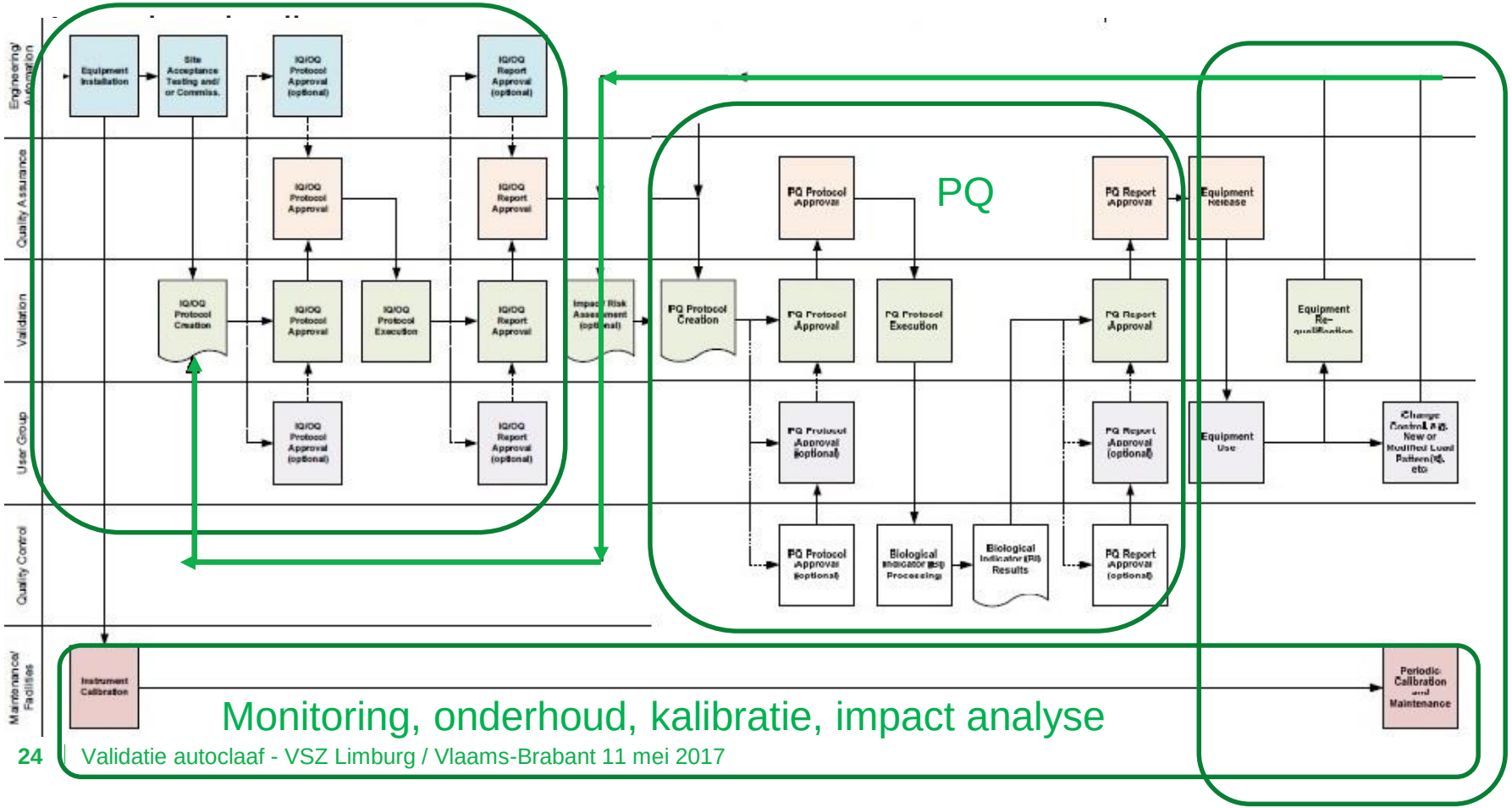
“Aan de hand van **gedocumenteerd bewijs**, met een hoge **betrouwbaarheid**, aantonen dat een **proces reproduceerbaar** zijn specificaties en kwaliteitsnoden behaalt.”

Validatie?

"Aan de hand van **gedocumenteerd bewijs**, met een hoge **betrouwbaarheid**, aantonen dat een **proces reproduceerbaar** zijn specificaties en kwaliteitsnoden behaalt."

- ✓ Gedocumenteerd bewijs
  - ✓ Meetdata, uitprint autoclaaf, gegevens indicatoren, ingevulde testscripts per test
- ✓ Betrouwbaar
  - ✓ Testmateriaal gekalibreerd + gevalideerd, valideur getraind, …
- ✓ Proces
  - ✓ Volgens procedures / gebruik van autoclaaf door ziekenhuis
- ✓ Reproduceerbaar
  - ✓ Tijdens initiële validatie – uitvoering in drievoud (parameterverificatie)
  - ✓ Na ingebruikname periodieke monitoring, onderhoud, validatie + impactanalyse

Validatie?


IQ/OQ
PQ
Engineering/ Automation
Quality Assurance
Validation
User Group
Quality Control
Maintenance/ Facilities
Equipment Installation
Site Acceptance Testing and/ or Commiss.
IQ/OQ Protocol Approval (optional)
IQ/OQ Report Approval (optional)
IQ/OQ Protocol Approval
IQ/OQ Report Approval
IQ/OQ Protocol Creation
IQ/OQ Protocol Execution
PQ Protocol Creation
PQ Protocol Approval
PQ Protocol Execution
PQ Report Approval
Equipment Release
Equipment Use
Biological Indicator (BI) Processing
Biological Indicator (BI) Results
Instrument Calibration
Periodic Calibration and Maintenance
Monitoring, onderhoud, kalibratie, impact analyse

Bedankt voor uw aandacht!

Tom Kerkhofs – Business Development Life Sciences

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