Kuijpers

Commissioning als basis voor kwaliteit

Paul Joosten
20 oktober 2016

Over Kuijpers

4 generaties familiebedrijf sinds 1921

Meer dan **950** medewerkers

Met **10 vestigingen** altijd een aanspreekpunt in de buurt

Kuijpers Controlled Environments

Cleanrooms
ASML te Veldhoven
Proces beschermen tegen omgeving

Containment
Eramus MC te Rotterdam
Omgeving beschermen tegen proces

KENMERKEN:

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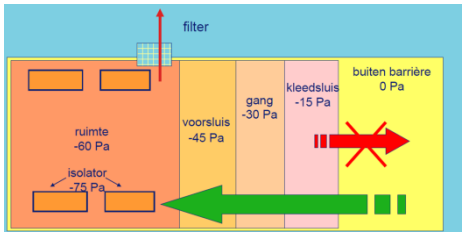

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Faalkosten

Eerste Kamer der Staten-Generaal

Over de Eerste Kamer ▾ Kamerleden ▾ Activiteiten ▾ Kamerstukken ▾

Inhoud
Introductie
Stand van zaken

34.453
Wet kwaliteitsborging voor het bouwen

Wet kwaliteitsborging

Geïntegreerde contracten

Uitgebreide inspectie (TNO en Halmos) in 70 gebouwen:

a) Gemiddeld energiegebruik gebouwen gemiddeld 25% hoger dan ontworpen.
b) Meer dan 70% van de klimaatinstallaties functioneren niet volgens het ontwerp: veel comfortklachten als gevolg
c) 90% comfort problemen komt door niet goed functioneren klimaatinstallaties.

Oorzaken:
- 15% ontwerpfouten
- 85% gebrekkige oplevering en gebrekkig onderhoud

Rapport TNO & Halmos, BREEAM, etc.

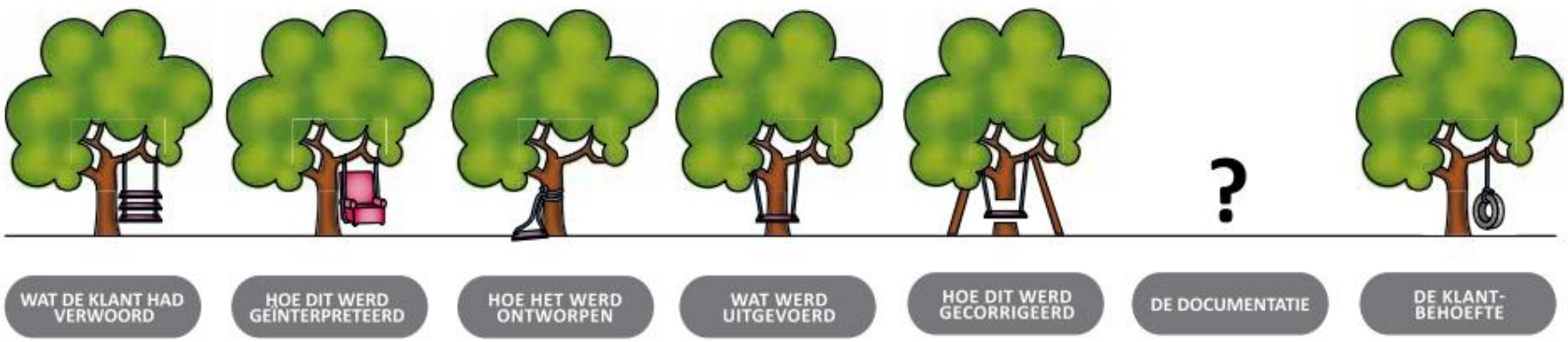
Trends

Wat zien we in de wereld om ons heen gebeuren?

‘Quality = fitness for use’

Dr. Joseph Juran, 1974

Kwaliteit → zo gaat het in de praktijk

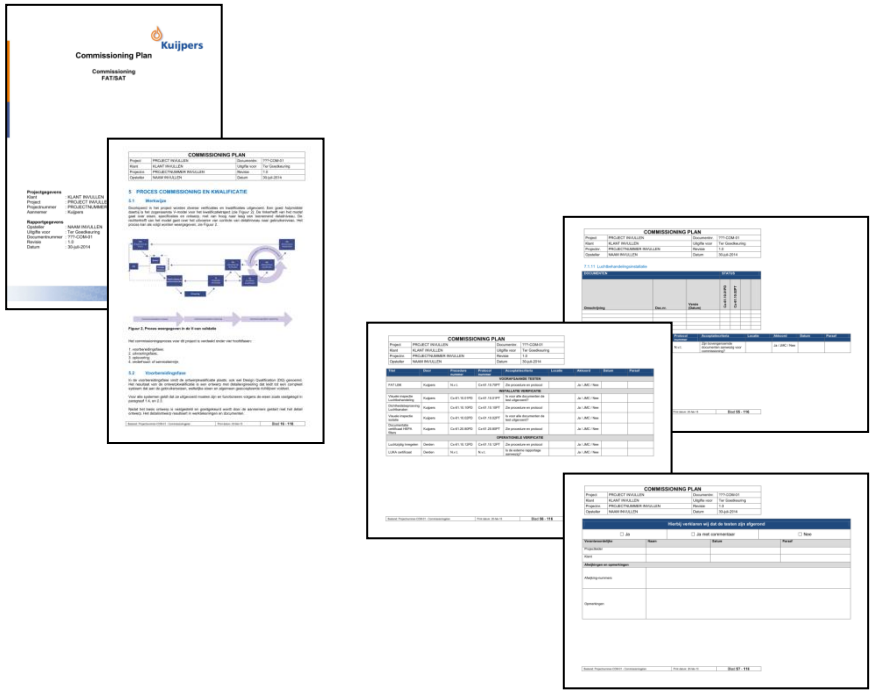


Wat is kwaliteit?

Kwaliteit ≠

Voldoen aan wens klant ≠

Impliciet

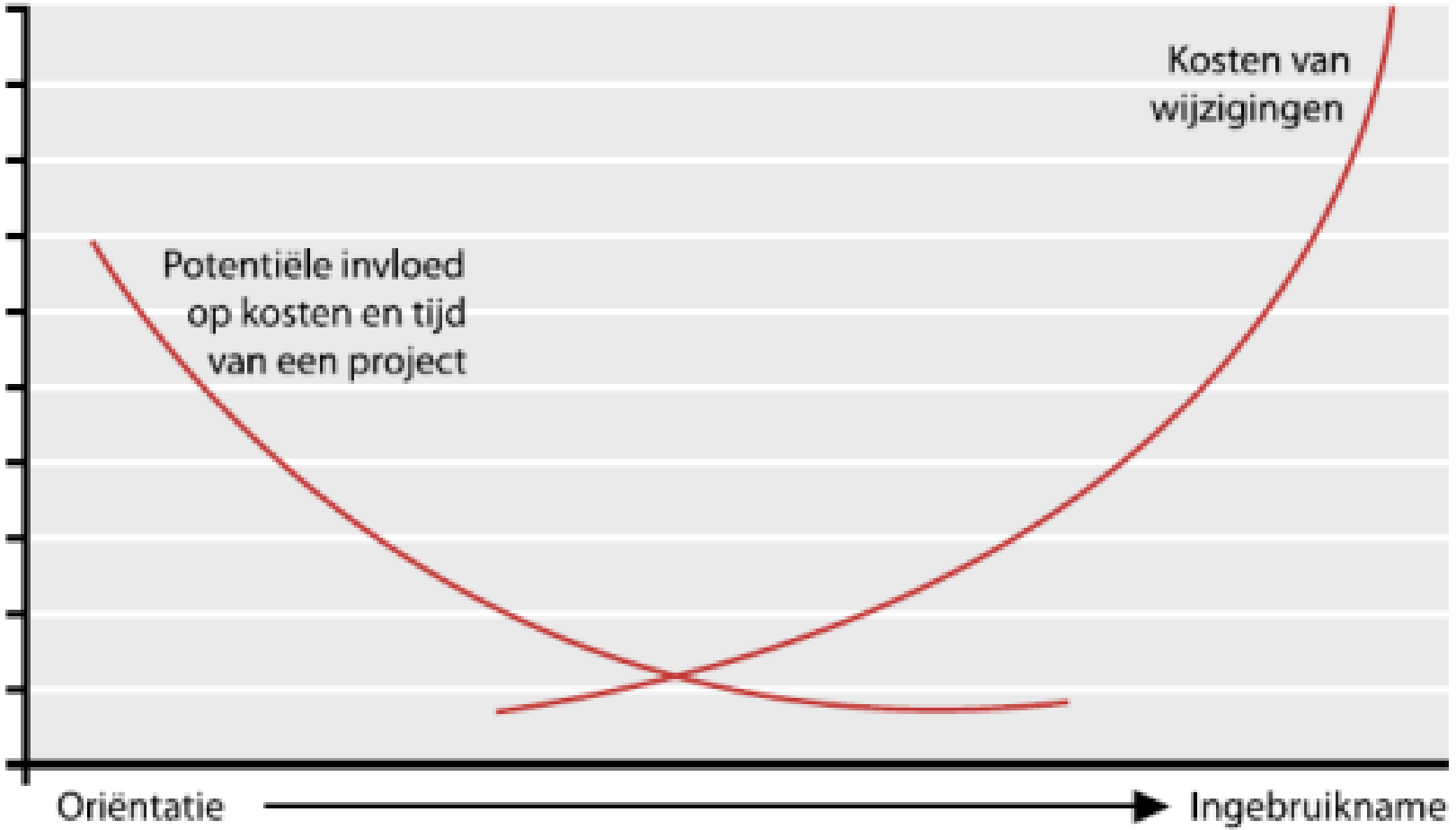


Expliciet

Kwaliteit “fitness for use” behaal je door:

Het Impliciete - Expliciet te maken

Invloed op kosten, kwaliteit en tijd



Wat denkt u dat commissioning is?

ISPE 2001-2007:
Een goed geplande, gedocumenteerde, gemanagede engineering aanpak voor de start-up en overdracht van faciliteiten, systemen en apparatuur aan de eindgebruiker.
Deze aanpak resulteert in een veilig en functioneel geheel dat voldoet aan vastgestelde ontwerp vereisten en verwachtingen van belanghebbenden.

Connecting a World of Pharmaceutical Knowledge

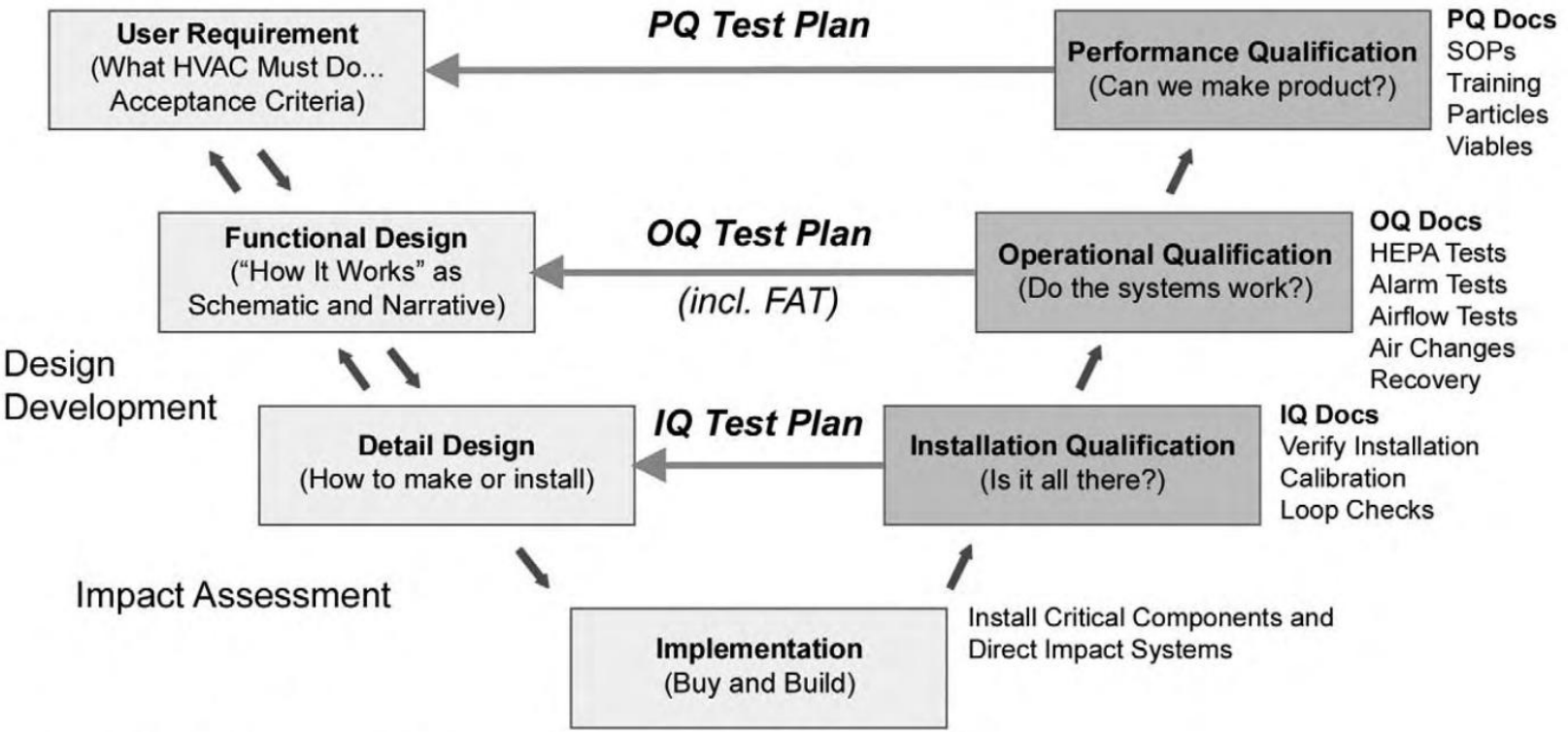
Commissioningproces

Het commissioningsproces omvat in hoofdzaak vier fasen:

Commissioning tijdens voorbereidingsfase.
Commissioning tijdens uitvoeringsfase.
Commissioning bij oplevering.
Commissioning bij onderhouds- of servicetermijn

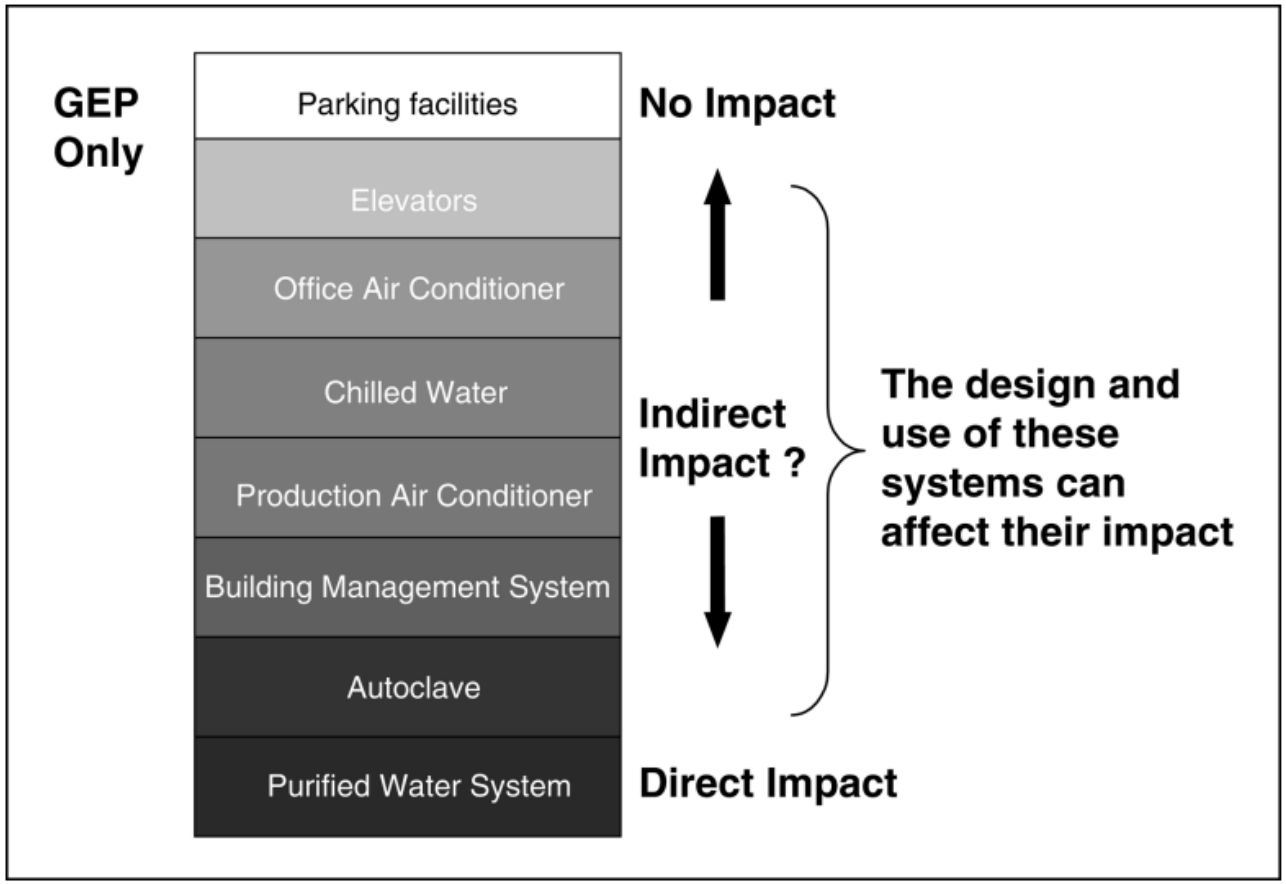
V-model

Figure 5.9: Qualification V-Diagram for HVAC



Hoe bepalen wat belangrijk is?

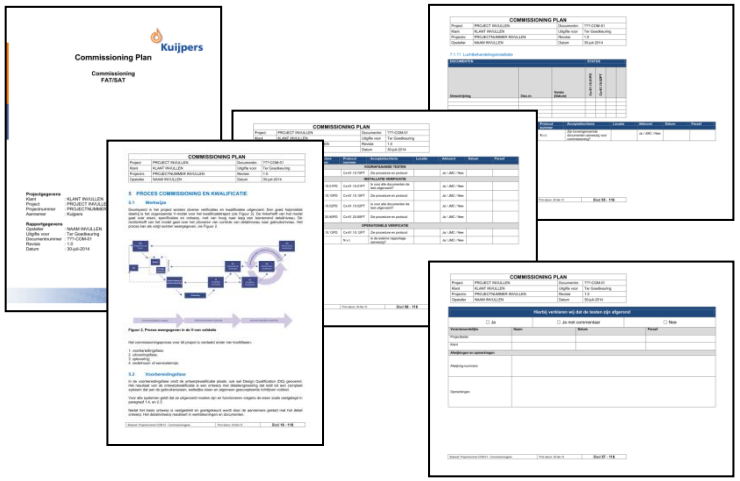
Figure 2-1 The Impact Spectrum



Kuijpers

Hoe geef je een commissioning proces vorm?

- **Start vanaf dag 1**
- **Begin met het Commissioning plan**
- **Positioneer het onafhankelijk**
- **100% maar geen overkill**
- **Vastleggen**
- **Maak het laagdrempelig door het aan te laten sluiten bij het proces**
- **Integraal**



Commissioning in de voorbereiding

Design Qualification (DQ)

Hoe doe je een DQ?

Project code:	RPHPR15001	RPH Eindhoven Relocation User Requirement Specifications	Doc. code:	RPHPR15001_URS_02
Site:	RPH Eindhoven		Issue date:	23-Feb-15
Revision nr:	02		Page:	13/15

Nr.	Description	Acceptance Y/N
142.	All control systems that affect the quality of the cleanroom environment or the recording of monitored conditions are to be designed to comply with Eudralex GMP Volume 4, Annex 11.	
	Electrical	
143.	Lighting levels within the cleanroom and the cleanroom changing room are not to be less than 1000 Lux at working levels.	
144.	High frequency luminaires are to be used.	
145.	Adequate emergency luminaire is to be installed.	
146.	Lighting units are to be set flush into the ceiling panels and should be ingress protected from above and below to prevent particles entering.	
147.	Easy access from the technical area, without disruption of the cleanroom or changing room integrity should be possible.	
148.	Diffusers must be of a low particle shedding material, and are to be resistant to repeated cleaning and sanitation with chemicals.	
149.	Utility socket outlets are to be provided. They are to be flush fitting where possible and easily cleaned.	
150.	Fire exit luminaires are to be installed above the exits	
	Communications/Data	
151.	Provisions for telephone/data points are to be provided. They are to be flush fitting where possible and easily cleaned.	
152.	Intercom between cleanroom and adjacent areas are to be provided. They are to be flush fitting and easily cleaned.	
153.	WIFI access linked to the GE systems is to be provided. They are to be flush fitting and easily cleaned.	
154.	A music/alarm/evacuation system is to be provided.	
155.	An access control system is to be provided.	
156.	A CCTV system is to be provided in the exit area.	
157.	A security system according security requirements of the KEW license is to be provided.	
	Fire protection	
158.	Fire detectors, call points and sounders are to be provided.	

4.5 *Testing and Commissioning*

Nr.	Description	Acceptance Y/N
159.	All clean areas shall be tested for compliance with ISO 14644	
160.	Environmental cleanliness in enclosed spaces.	
161.	Measurement of airborne particulate contamination conditions.	
162.	Measurement of air velocity in LAF cabinets.	
163.	Measurement of air temperatures and humidity.	
164.	Test of lighting levels.	
165.	Test of air pressure differentials.	
166.	Confirmation of air flow patterns.	
167.	Test noise levels.	
168.	Integrity testing HEPA filters.	
169.	Testing of viable particles.	

4.6 *External Finishes*

Nr.	Description	Acceptance Y/N
170.	All external finishes of the facility will be compatible with the main building and surroundings.	
171.	Surfaces should be easily cleanable and disinfectable and durable.	
172.	Walls of main corridors are to be protected against wheeled traffic with fenders.	

DESIGN QUALIFICATION			
Project	RPH Eindhoven Relocation	Documentnr.	20151026**Fout! Verwijzingsbron niet gevonden.**
Klant	GE Healthcare	Uitgifte voor	Ter Goedkeuring
Projectnr.	20140108	Revisie	1.0
Opsteller	R.Oomen/ H. van den Oever	Datum	26-okt-15

4 VERIFICATIE VAN EISEN

Eis Nr.	Omschrijving uitwerking van de eis / specificatie in het ontwerpdocument	Akkoord [P / PWC / F]	Opmerkingen (restpunt volgnummer)
1	Provide a suite of rooms with environmental control of particulate contamination, temperature, humidity and pressure. / Er wordt voorzien in gecontroleerde ruimtes.	P	
2	The cleanroom area is to be classified as a radiological B area.	PW	Zie punt 2.
3	As a cleanroom area, it is to be designed as pharmaceutical Grade C in accordance with Eudralex, The Rules Governing Medicinal Products in the European Union, Volume 4: Annex 1 Manufacture of Sterile Medicinal Products. It will be operated as grade D in accordance with GMPz.	P	
4	Removable "knock out" panels are required for emergency ex	P	
5	Materials of construction should be non-flammable and have particle non- shedding, non-porous and resistant to supporting microbial growth properties.	PWC	Not non flamma
6	All vision panels and windows shall be double-glazed and designed to fit flush into the wall panel system on both sides.	PWC	
7	All vision panels and windows shall be double-glazed and designed to fit flush into the wall panel system on both sides.	PWC	
8	It is accepted that the areas and sizes of some rooms will be modified to suit and fit the total area available (GE approval required for changes, and final drawing needs to be signed).	P	
9	All wall finishing must not shed particles, are suitably smooth and free from cracks, cavities, steps and ledges.	P	
10	All corners and junctions are to be radiused, especially at foot-to-wall and wall to wall, so that effective cleaning is facilitated.	PWC	Not all have area's wall/wall and wall/ceiling
11	The finishing materials should neither generate nor hold a significant static charge.	P	
12	The finishing materials are suitable for effective and frequent cleaning and disinfection. Main cleaning agents used are 70% IPA, 70% ethanol with hydrogen peroxide and chlorine solution, but other cleaning agents might be used as well.	PWC	except for the coated elemen
13	The cleanroom is to have glass panels to adjacent rooms B/C/D/G/J and to corridor (L) around the cleanroom.	P	
14	The glazed panels are to be sealed double glazed units that are to be flush mounted on both sides.	PWC	fire- ant wall
15	The wall between the cleanroom and dispatch area (J) will need to have at least 2 material pass through hatches (#1 and 2).	P	
16	The hatches will have an integrated HEPA filter and active air extraction.	F	No HEPA filt equipped wi
17	The material pass through hatches #1&2 will be large enough to pass through a rack filled with at least 8 syringes.	P	
18	These hatches(#1&2) will need to be interlocked to prevent the doors to be opened at the same time.	P	
19	Clear windows are to be provided at both points of the transfer hatches to allow a line-of-sight view between them.	P	

Traditioneel

Digitaal

Commissioning tijdens de uitvoering

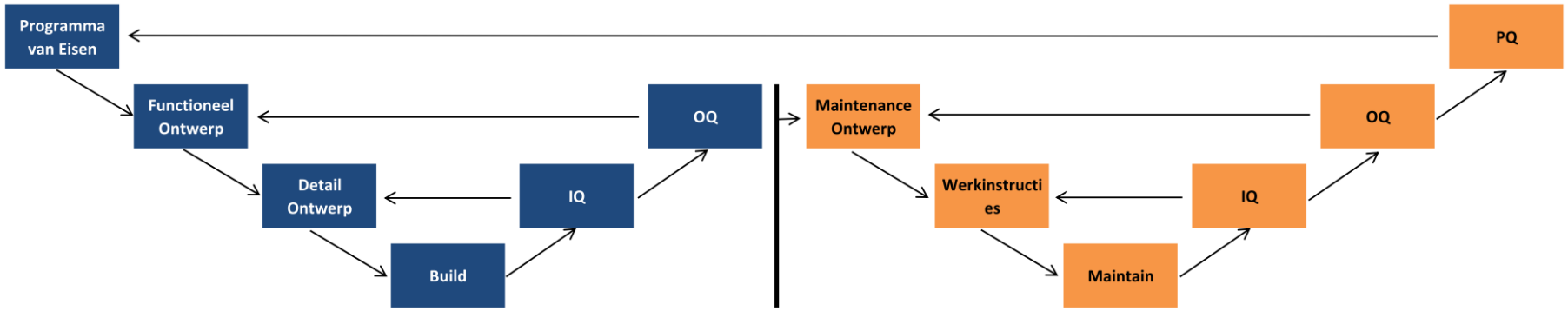
IQ, OQ

Hoe doe je IQ en OQ?

- **Standaard procedures**
- **Project specifieke documenten uit ontwerpfase**
- **Stap voor stap:**
  - Visuele inspecties
  - I/O testen
  - Functionele testen
  - Integrale testen
- **Opname rondes integreren**
- **Maak afspraken over witnessing**

Commissioning tijdens de oplevering

Eind testen en vergeet training niet



W-model

Ook commissioning tijdens de onderhoud- & beheerfase

Vragen?