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health and high tech generator

future diagnostics

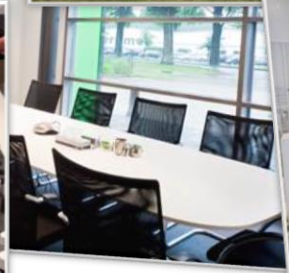
“From Immuno Assay to an IVD Product”

Mike Martens, Scientific Business Executive

Facts of Future Diagnostic Solution B.V.

- Independent Company, founded in 1997
- Based in Wijchen, the Netherlands
- Internationally oriented (EU, US and JPN)
- 3500 m^2 facility
- Over 70 employees
- ISO13485:2016 certified
- FDA registered site (inspections in 2004, 2008, 2011 and 2016)

Future Diagnostics Solutic



Our Development Services

- Full (immuno) Assay Development
- IVDR Analytical Performance studies
- Verification, Validation & Stability
- Point-of-Care Test Services
- (Accusphere) Lyophilisation

Our Manufacturing Services

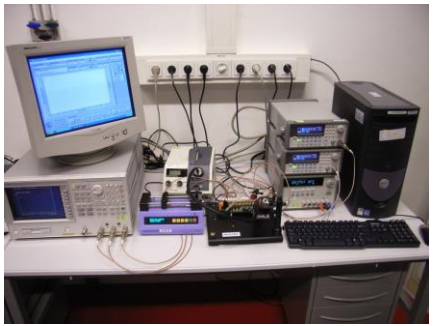
- Assembly of (Immuno) Assay Kits
- Bulk Production of Solutions & Beads
- Product Filling, Capping & Labelling

Customers


NOVARTIS
IDEXX LABORATORIES
BECKMAN COULTER
PHILIPS
Volition
arocell
BGMEDICINE
ULTRAPLACAD
QUOTIENT
DSM
BRIGHT SCIENCE. BRIGHTER LIVING.
Ceva
SIEMENS
Stago
Agilent
ids
immunodiagnosticsystems
DIA Source
MyCartis
Collaborate to innovate
BIO-RAD
BIOCDx
Canon
CANON MEDICAL SYSTEMS
sysmex
TECAN.
BIOCARTIS
BIOVICA
aptec
Abbott
janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson
TOSOH
bioeq
BANYAN
BIOMARKERS
BIOMÉRIEUX
Ortho
Clinical Diagnostics
and you...?

From Quality Assay to IVD Product

Lab model



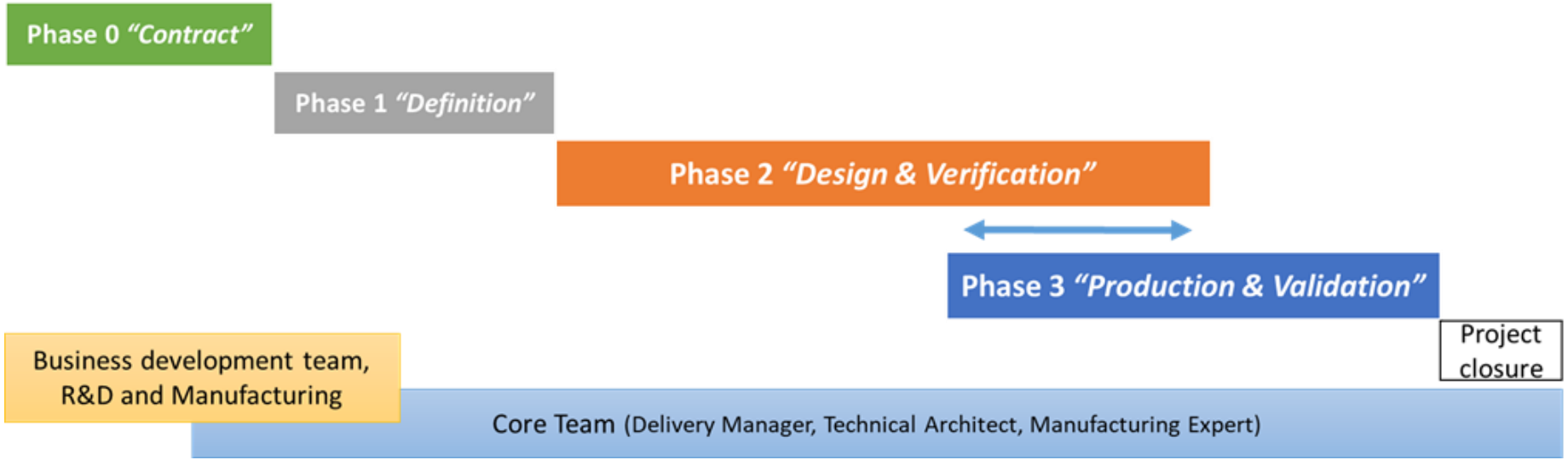
How Long?

> 10 years

Hand held analyzer

New Product Development Process (NPDP)

How we work



From Quality Assay to IVD Product

- Design Freeze
- Change control (documentation system)
- Manufacturability
- Validation of manufacturing processes
- Scale-up of manufacturing processes
- Supply chain of the different critical raw materials
- Regulatory landscape in the different countries

From Quality Assay to IVD Product (i.e. ELISA)

Phase	Description	# months	Hours				Total hours
			DT/DE	TA/DM	MFG staff	Other staff	
Definition	Pre-feasibility study	2	320	225		40	585
Design	Design Freeze	7	960	675	100	120	1,855
	Create phase 2 documents	7	240	60		15	315
Verification	Create plan(s) & 2 reviews	1		40			40
	1 lot @ R&D & testing	3	720	340	50	75	1,185
	Create report(s) & 2 reviews	1	10	40			50
Production	Update provisional MFG & QC docs	0.5	20		20	5	45
	3 lots @ MFG	3	480	290	1060	85	1,915
	Finalize MFG & QC docs	0.5	20		20	5	45
Validation	Create plan(s) & 2 reviews	1		40			40
	Testing	2	640	225	20	60	945
	Create report(s) & 2 reviews	1		40			40
Stability	After validation	1	160	40			200
Total		16*					7,260
	* Note: Items are done in Parallel						
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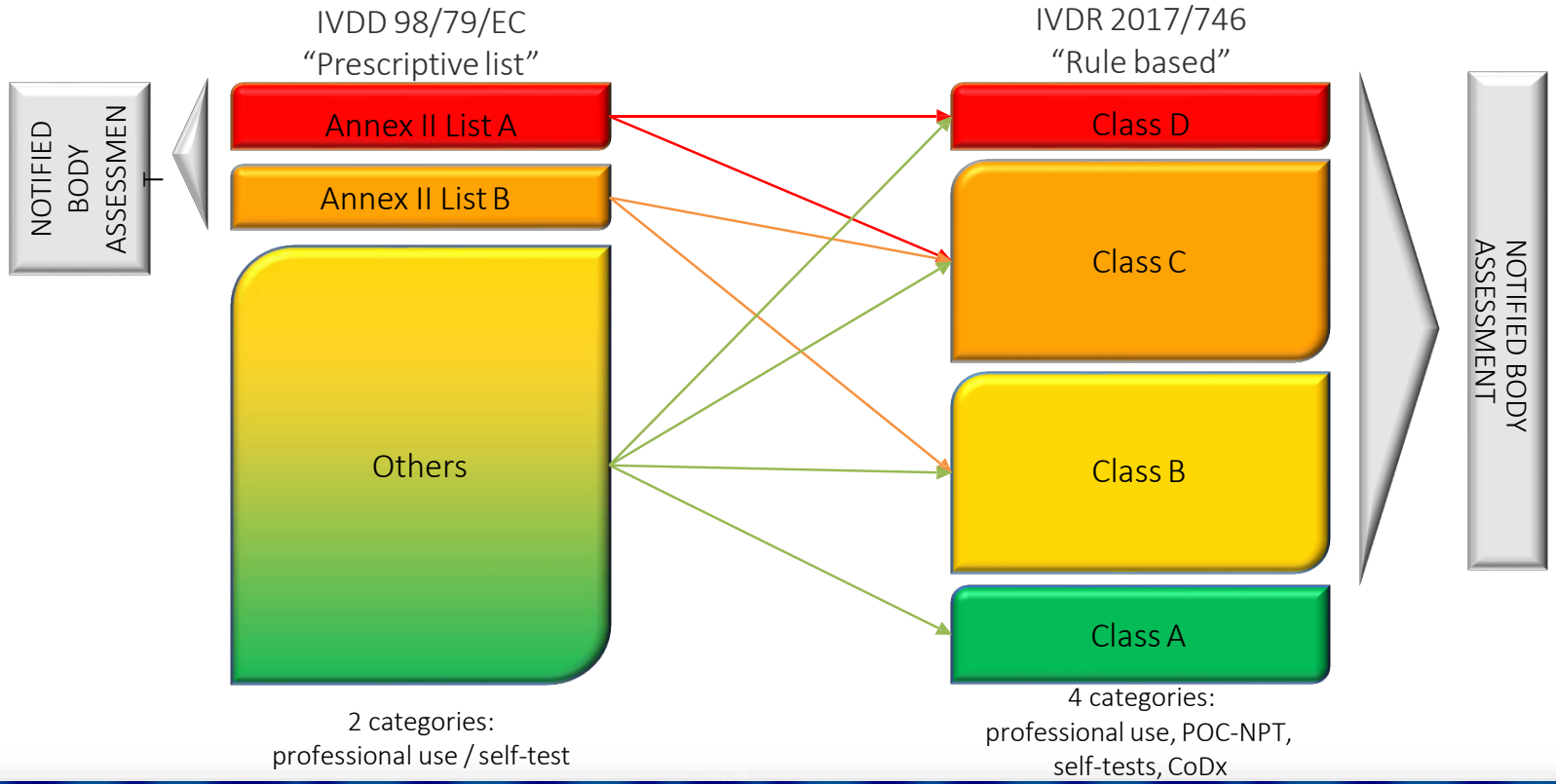
From IVD-D to IVD-R



From IVD-D to IVD-R (Clinical Evidence)

Scientific Validity

Scientific validity of an analyte means the association of an analyte to a clinical condition or a physiological state;

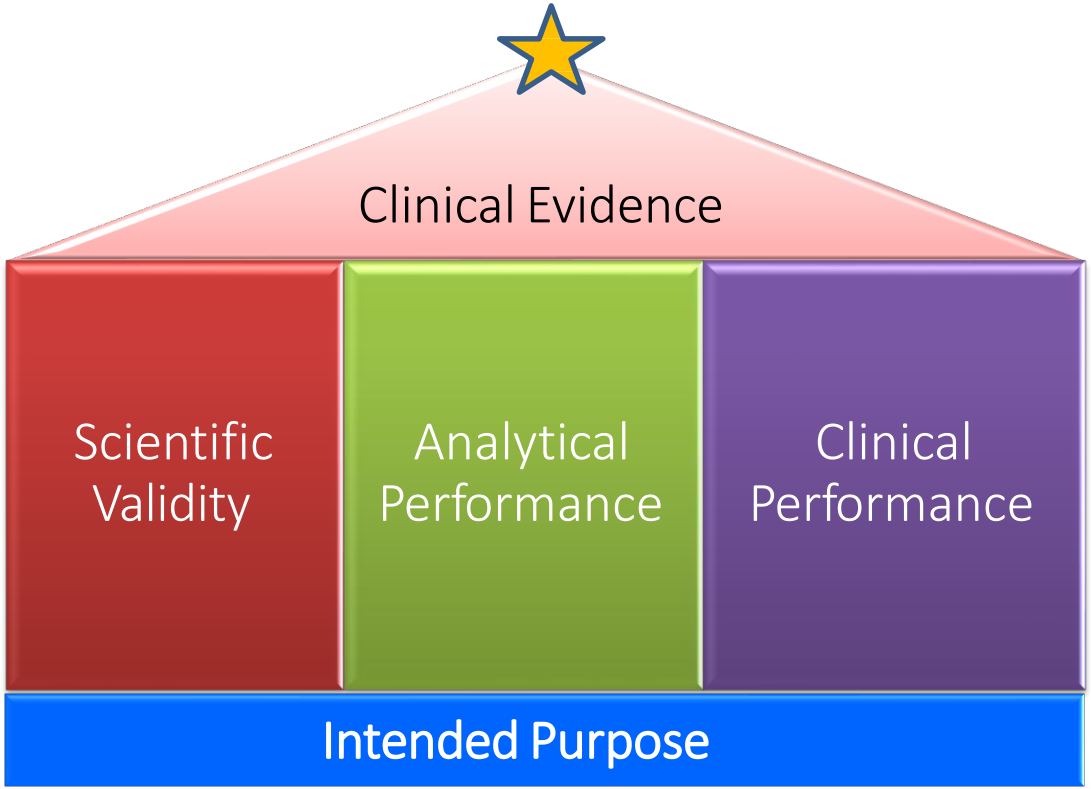
Analytical Performance

Analytical performance means the ability of a device to correctly detect or measure a particular analyte

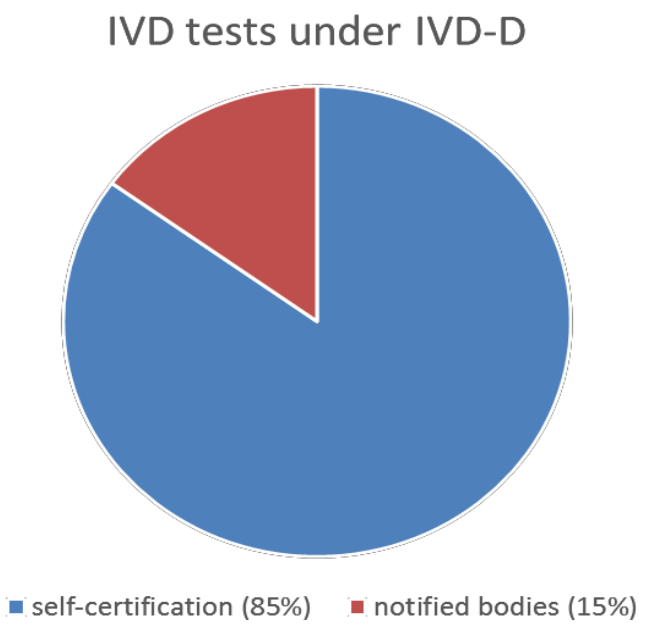
Clinical Performance

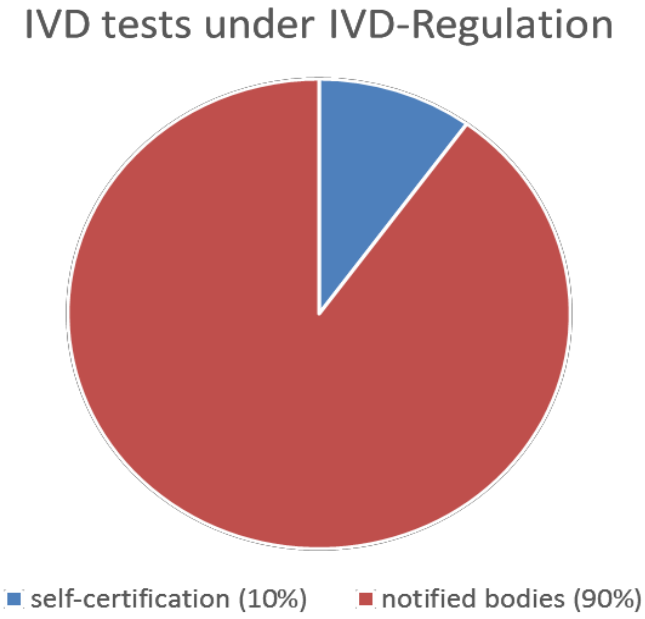
Clinical performance means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user

From IVD-D to IVD-R (Clinical Evidence)



From IVD-D to IVD-R





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Thank You Danke Merci Gracias
Bedankt Obrigado ありがとう
Tack Kiitos Takk Grazie Dziękuję