

Applikon Biotechnology

Turn-key solutions for vaccines biosafety and production



Applikon Biotechnology

- Largest privately owned bioreactor company in the world
- Started in 1974 by Jan van Burg
- Keywords:

- Reliable
- New technologies
- Long term customer relation
- Micro scale to production scale systems
- Local experts for sales, service and support
- Bioreactor systems only
- Daughter companies in UK, USA, China



Jan van Burg







World Distribution



Experience in large scale systems

- Vaccine & Mab-market
- Global supply
 - Project communication
 - Installation
 - Validation
 - Field support
- Separate skids and integrated skids
 - Automation: Standardized Allen Bradley & Siemens PLC
- Turnkey delivery & Integration (Storage & Supply tanks CIP, Utilities, Centrifuges, SCADA ...)





Individual skid or super skid







Vaccines projects experience

Europe & Americas	Asia	Rest of World
Bilthoven Biologicals/SII	China National Biotech Group (SIBP, Lanzhou institute, Kunming institute)	Vacsera, Egypt
Intravacc	Beijing Minhai	
Chemocomplex, Hungary	Walvax	
Merial, USA & France (veterinary)	Bravovax	
GSK, USA, UK & France (veterinary)	Biofarma	
Sanofi, USA & France	Serum institute India	
	Pasteur Institutes Kasauli and Conoor, India	

Role of bioreactor supplier in Biosafety

- Essential collective efforts to ensure biological safety for a clean and safe environment
- Containment principle and monitoring aspects of bioreactors
 - Sealing arrangement
 - Pressure relief systems
 - Sampling systems
- Measuring and monitoring containment:
 - Number of tests prior to the operation (i.e. pressure hold test)
 - Planned Maintenance and Training



Case Study: Manufacturing a cGMP vaccine production plant

- Fully integrated production upscale facility
- Full cGMP
- Scalable systems and transfer lines
- Integration of 3rd party systems
- Fully automated operation



Human vaccine producing company

- Buffer preparation vessels
- Inoculation fermenters
- Scale-up fermenters (up to 1500L)
- Addition tanks (Glucose feed & buffers)
- Continuous centrifuge
- Harvesting vessel
- Collection vessels
- Kill tanks
- Transfer lines
 - CIP/SIP fully automated
- Total 14 vessels and transfer lines

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cGMP case study Human Vaccine



User Requirement Specifications

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		2	Capacity	Working volume Total volume	: 1000 Liter : 1500 Liter			
		3	Design/Feature	 cGMP Agitation Air inlet 1 Air inlet 2 Air outlet Mechanical foam br Addition line 1 Included compatil 	: Stirrer : - Overlay, air : - Sparger, air + O2 : - Housing filter with h reaker : 200 L/min, From : housing filter for medium ble with filter cartridge Pal	neating elemer MBR (housing filter I B1NF7PH4)	nt -	

From specifications to operational product

- Engineering (Applikon)
- Qualification (Applikon)
- Production (Applikon)
- Qualification (Applikon)
- FAT & Training (Applikon)
- Packing & Shipping (Applikon)
- Unpacking & Installation (Applikon)
- SAT & Training (Applikon)
- Performance Qualification (Customer)
- Validation (Customer)
- After sales support (Applikon)



PFD made according URS



P&ID made according URS





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options

BIOTECHNOLOGY

Project Management Center

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	Home page
	Summary page
	ToDo list Calendar
	Forum search
	Log out
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_	Project:
_	 Demo Project
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	Edit project
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Owned by:	Piet den Hartog
Created on Deadline:	2015-May-30 by Piet den Hartog 2017 May 28
Priority:	Normal
Status:	Planned Project
Usergroup:	demoproject (This project is only accessible by members of the usergroup)
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4-Software (Software)

- 4) SCADA (Planned (not active)) [Plet den Hartog]
 - 4.1 Release SCADA Configuration Specification (Planned (not active)) [Plet den Harlog]
 - 4.2 Release Configuration Software SCADA (Planned (not active)) [Plet den Harlog]

5-Qualification (Qualification)



6-Transport (Transport)



7-Installation / Commissioning (Installation / Commissioning)

- 7) Installation / Commissioning (Planned (not active)) [Plet den Hartog]
 - 7.1 Installation / Commissioning (Planned (not active)) [Plet den Hartog]
 - 7.2 Site Acceptance Test (Planned (not active)) [Plet den Hartog]
 - 7.2.1 Release SAT Protocol (Planned (not active)) [Plet den Hartog]
 - 7.2.2 Perform SAT (Planned (not active)) [Plet den Hartog]

8-Training (Training)

8.1 Training (Planned (not active)) [Plet den Hartog]

3D CAD design











Factory Acceptance Test

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Unpacking & Moving

Start of installation

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Site Acceptance Test

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Turn Key Solution



Case Study 2- Lesson to be learned Vaccine manufacturer RESULTS

- cGMP production
- No input from supplier at the initial stage

- Overqualified system
- Cost does not fit to the projected budget

2 YEARS LATER:

- New specifications
- Final calculation
- Final documentations
- Moving on to next step

Supplier

- Depending on manufacturer specifications
- No input on the specifications

Analyzing

- Over priced system
- Recalculation
- Revision of all documentations



system



Value Proposition of the Netherlands Vaccine Initiative (NVI)





Why this Vaccine Initiative?

We help you to realize vaccine manufacturing capabilities, in time and performing as intended, by providing

- Technology transfer and training
- Translation of process design into a flexible facility
- Validation of the process and facility
- Meet the international regulatory guidelines





The unique offering of the Netherlands Vaccine Initiative

To create state of the art vaccine manufacturing capabilities based on established & transferable platform vaccine technologies

By means of an integrated multidisciplinary approach ensuring:

- Cost effectiveness, by doing it first time right
- Fast track delivery leading to early return on investment
- Access to global vaccine markets
- Thorough understanding of your critical business & technology processes



The Netherlands Vaccine Initiative offers you (1)

- Vaccine process and analytical technology
 - \rightarrow Proven technology, low risk
- GMP process and facility engineering
 - \rightarrow Support and execution for successful validation
 - \rightarrow Acceptance by international and national regulatory authorities
 - \rightarrow Facilitate smooth licencing process for export
- Sustainability engineering
 - \rightarrow State of the art energy efficient, reliable and flexible process and facility concepts
 - \rightarrow Responsible to society and environment













Profile (1)

The Netherlands Vaccine Initiative consists of four companies. Per company they bring the following value to the Initiative:

Intravacc

- The Institute for Translational Vaccinology, is an experienced, not-for-profit R&D organization. We optimize vaccines, vaccine processes and vaccine technologies.
- Developing and improving vaccine design, production processes, analytics and technologies
- Share and transfer our knowledge and technologies to public and private partners worldwide and work on collaborative R&D.

Applikon

- Privately owned world leader in developing and supplying advanced bioreactor systems with a focus on (human) healthcare.
- A global network of well-trained local distributors to guarantee good and fast local support for our customers.

Profile (2)

Xendo

- XENDO focusses on product and process quality and regulatory aspects.
- Process engineering and validation capabilities, enable the translation from laboratory scale concepts to a full-fledged manufacturing facility.
- Qualification, validation, QA system implementation and regulatory support services ensure GMP and regulatory compliance of the product and the process

Deerns

- Deerns is an international, independent technical consultancy and engineering firm, that creates a **sustainable, comfortable and safe built environment**
- Providing feasible solutions, based on innovative designs. Deerns delivers solutions for facilities in which contamination control is paramount.
- Decades of expertise and experience in developing, designing and putting into operation cleanrooms and laboratories.



Our Project Execution Vision provides:

- An integrated project approach
- A joint approach to achieve regulatory compliance and licensing
- Up front specification before realisation
- Continuous communication on the project status
- Effective project control measures



Vaccine Development



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Deliverables Vaccine Development

- Fast-track new vaccine concepts development based on proven technologies
- Process and analytical development up to GMP-grade pilot-scale based on bacterial and viral vaccine development platforms
- Technology Transfer package and hands-on training modules, and active support for vaccine production and quality control



Facility Development



Deliverables Facility Development

- Complete functional process and facility design
- Project management, Monthly progress reports on progress, costs and quality
- Procurement packages for contractors defining performance, scope, timing and warranties
- Managed construction site of equipment and facility
- Facility construction and delivery management, installation and commissioning protocols
- Qualification Plan, Qualification Protocols, Execution and reports
- Validation (Master) Plan, Protocols, Execution, Reports
- Quality System

• Support to Registration Dossier



Your solution: The Netherlands Vaccine Initiative

Thorough understanding of your critical business & technology processes

Integrated multidisciplinary approach ensuring:

- Cost effectiveness, by doing it first time right
- Fast track delivery leading to early return on investment
- Access to the global vaccine market









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