PRAXIS

A publication by Bioengineering AG

Samsung BioLogics was founded in April 2011 and took only three years to establish itself as a global biotechnology contract manufacturer. One of the main reasons for this success was the fast-track execution of the Edison I project. The first Samsung BioLogics cell culture manufacturing facility took a mere 13 months to complete. In this issue of Praxis, we share the history of this unique and outstanding project.

B.IOENG.NEER.NG

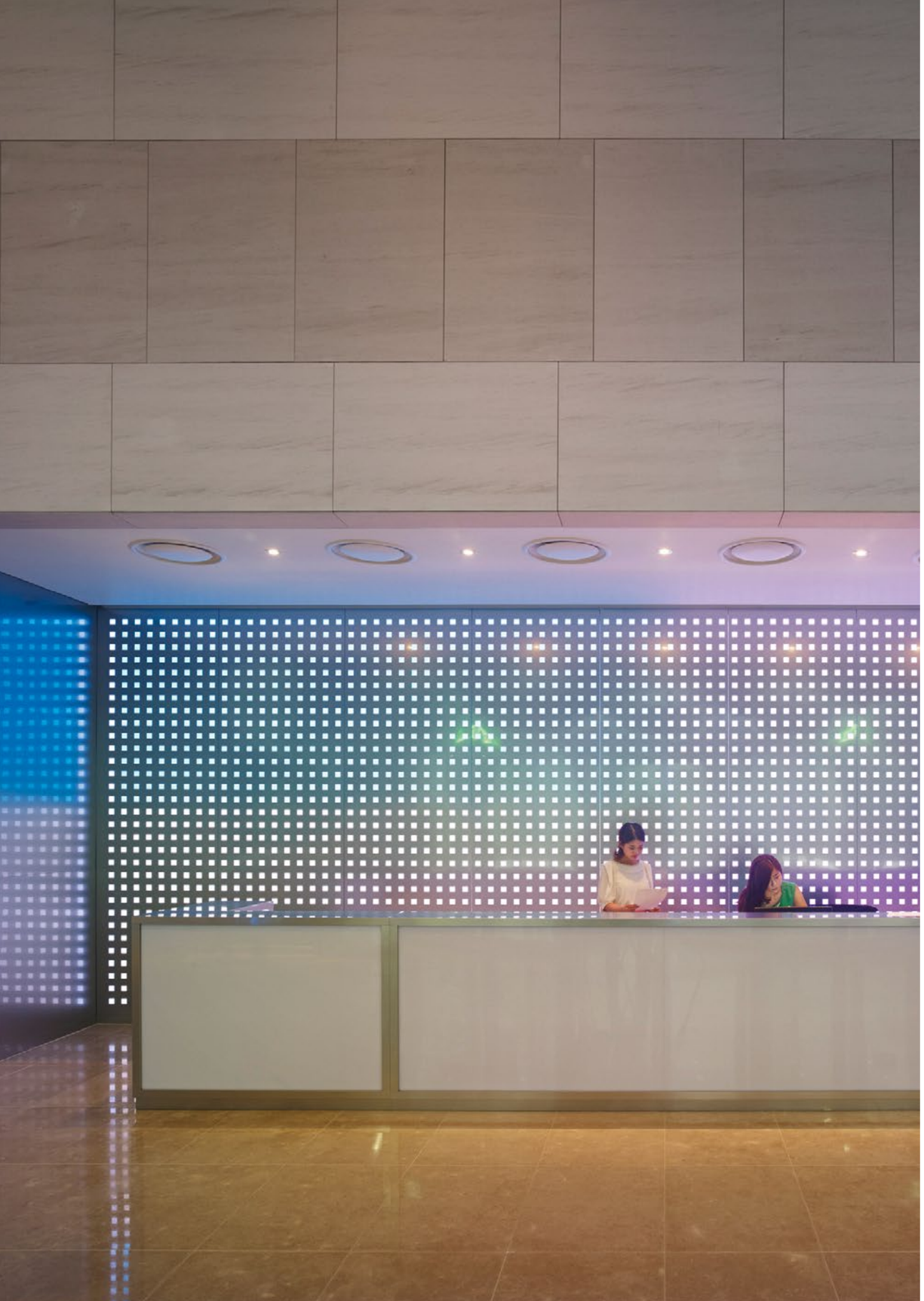
Bioengineering AG
Sagenrainstrasse 7, 8636 Wald, Switzerland
Telephone +41 (0)55 256 81 11, Fax +41 (0)55 256 82 56
info@bioengineering.ch, www.bioengineering.ch

Bioengineering –
Experience only specialists can have

Incheon, South Korea, 19:15

Content

Samsung BioLogics was established in April 2011 and has its headquarters in Incheon, South Korea. It was established as a joint venture between Samsung affiliate companies and Quintiles Transnational Corp. to become a leader in the biopharmaceutical industry.
Samsung has a long and rich history of research and development. The launch of its new biologics business builds on the company's past achievements and brings its unwavering technological leadership to the biologics sector. By making use of Samsung's quality, technology, and innovation, Samsung BioLogics will transform the global healthcare industry over the next decade.
One of the Samsung Group's core missions is to enhance the quality of human life. Samsung is committed to quality-driven manufacturing of biopharmaceutical products. Its customer-oriented business model supports both collaborative new drug development and high-quality, fast-turnaround contract manufacturing partnerships. Samsung's cutting-edge facility was constructed to be compliant with global cGMP regulations. It will provide the infrastructure for partnerships with industry leaders to develop, refine and distribute biopharmaceutical products worldwide.
Samsung BioLogics has pledged to make a difference in global healthcare.



Key points of Edison I

Samsung BioLogics plant 1 (Edison I) is one of the largest pharmaceutical facilities ever developed, built and commissioned in South Korea. The entire facility covers an area of 56,800 m², distributed over seven working levels. The six largest bioreactors have a production capacity of 5,000 l each. The engineering, construction and qualification of the facility was an extremely complex and demanding task. The project time of 25 months from laying the foundation stone to completing validation is a worldwide record for successful engineering, procurement, construction, validation (EPCV) and commissioning of a large-scale cGMP manufacturing facility.

Edison I
A state-of-the-art, multi-product biologics facility

Type	Facility for monoclonal antibodies and recombinant protein manufacturing
Cell culture capacity	30,000 l (6x 5,000 l bioreactors)
Purification	Flexible high-titer processes, centrifuging, depth filtration, chromatography
Fill and finish	Liquid/lyo vial filling, 2 lyophilizers, labeling and packaging
Development stage	Clinical and commercial
Regulatory compliance	US FDA, EMA and Korean MFDS
Floor space	56,800 m²
May 2011	Groundbreaking of the SBL 1st plant in Incheon, Songdo, South Korea
June 2012	Completion of mechanical work
June 2013	Ready for cGMP operation

Interview with Mr. Tae Han Kim, President and CEO of Samsung BioLogics

Insight into Samsung BioLogics and its business success, project execution of Edison I and quality assurance

Bioengineering AG: Samsung is a relatively new player in the biotechnology contract manufacturing sector, where it has been rapidly and remarkably successful. How did the idea to enter this business sector originate?

Tae Han Kim: We believe that the biopharmaceutical market will grow continuously due to an increase in the age of the population, an increase in the incidence of cancer and autoimmune diseases and an increase in the wealth of people all over the world.
The evolution of the biopharmaceutical industry will be accelerated by innovations in the life sciences and technologies based on genome science.
I believe that the pharmaceutical industry has reached a turning point in its evolution due to a change in the market demand from chemical drugs to biologics and the pressures of cost and price competition.
We now have to optimize the entire value chain of the biopharmaceutical industry.
Samsung is trying to explore new business opportunities in the current market growth and recent changes in the biopharmaceutical industry.
Samsung has done well in the IT business thus far, such as in digital TV sets, smart phones and semiconductors.

Now the company will be adding bio-tech and healthcare to its existing IT business.
Samsung will utilize its manufacturing expertise in the biopharmaceutical industry and wishes to contribute to further improvements in the health and life quality of society worldwide.

Bioengineering AG: We are four years down the line now since the project started - where do you stand in terms of your production facility?

Tae Han Kim: Samsung brings global biopharmaceutical capability through its fully integrated production facilities that offer process development, drug substance manufacturing, and drug product fill and finish services at a single location. In addition to its current biologics manufacturing facility in Incheon, Korea, the company is currently building a second facility, also in Incheon, which is expected to be completed in early 2015.

Bioengineering AG: What was the greatest challenge you experienced during the execution of the Edison I project?

Tae Han Kim: The extremely rapid project execution.

Bioengineering AG: Can you summarize the most salient points for a successful fast track project?

Tae Han Kim: Samsung started construction in May 2011 and completed its top quality biopharmaceutical manufacturing plant in December 2012, including 30,000 liters of mammalian cell culturing capacity.

Usually this process would take about four years, including basic design, detailed engineering, procurement, construction and equipment validations. Samsung has been able to complete all these activities within 2.5 years by concurrently processing its plant design, construction and equipment validation.
The concept of "concurrent processing" is nothing new, but you can only apply concurrent processing to biopharmaceutical plant construction when you can execute the design, construction and validation with top-quality control of each unit process, and then only when you can execute multiple unit activities with accurate time management.

Bioengineering AG: What were the reasons and influencing factors for selecting Bioengineering AG as the main supplier?

Tae Han Kim: Bioengineering AG is a very well-known partner for engineering and constructing major biopharmaceutical upstream facilities worldwide. Based on several bioengineering projects the company has undertaken in the Korean market, you have the necessary experience with local conditions, partners and culture as well. This global know-how and local experience were important to us to assure on-time delivery of equipment and completion of the project. As well as the delivery reliability, the quality of Bioengineering's work and equipment convinced us and meets our standards and requirements.

Bioengineering AG: How did Bioengineering support you in reaching your milestones?

Tae Han Kim: Of crucial importance to the success of such a project is its project team. Bioengineering did support us with a very strong team which, depending on the task at hand, brings together specialists and generalists, experienced practitioners and young professionals. The project teams at Samsung Biologics and Bioengineering established an exemplary cooperation, which allowed for a time-saving and direct solution-finding process. Open issues were proactively clarified to minimize any side effects on the project milestones.

Bioengineering AG: Regulatory authorities and customers in the pharmaceutical field have high quality demands. What is your approach to quality?

Tae Han Kim: Samsung BioLogics quality systems ensure that all equipment and systems are maintained throughout cGMP production and that our products are of a high quality. The Samsung BioLogics quality and compliance team is fully committed to high-quality management of continuous improvement through CAPA effectiveness checks and evaluations, quality risk assessments, our supplier audit program, in-process management review and a self-inspection program.

Bioengineering AG: What kinds of customers and partners have you attracted thus far?

Tae Han Kim:
July 2013: A strategic manufacturing partnership with BMS to manufacture multiple commercial products.
October 2013: A strategic manufacturing partnership with Roche to manufacture multiple commercial products.

April 2014: An expanded strategic manufacturing partnership with BMS for an additional drug substance and drug product.

Bioengineering AG: Why is Samsung BioLogics the ideal contract manufacturer?

Tae Han Kim: We believe that there is room for further optimization of the biopharmaceuticals value chain.
Small biotech companies are particularly good at inventing innovative biologics products, while big pharmaceutical companies are good at invention, development, marketing and sales.
Manufacturing does not appear to be a strong point for either, thus Samsung will concentrate on manufacturing the biologics products.
Samsung is trying to maximize client satisfaction by increasing the CMO service value and by reducing the service price, while adhering to its global standards of top quality and regulatory compliance.
This allows biotechnology and major pharmaceutical companies to avoid capital expenditure and/or utilize additional manufacturing capacity with improved flexibility.

Bioengineering AG: What are some of the key strengths you see in Samsung BioLogics, the goals that you have set for the company for the next few years and what is your strategy to reach them?

Tae Han Kim: Samsung is financially stable and committed to biologics with a $2b investment.
Samsung is focusing on contract process development and manufacturing services, expecting economy of scale and a competitive supply chain.
We have just completed a 30,000-liter mammalian cell culturing plant for higher titer products.
Now we are designing and starting construction of a 150,000-liter plant with a target completion date in 2015.
We plan to build a microbial fermentation plant by 2016 to meet the increasing manufacturing demand.
We expect a lot of cost savings from the economy of scale effects by building the high-quality and big-capacity plants at the same site.
Samsung currently has the best manufacturing practice in the biologics industry and execution excellence in plant design, construction and cGMP operation.

Bioengineering AG: What is your final message to the readers of Samsung Praxis?

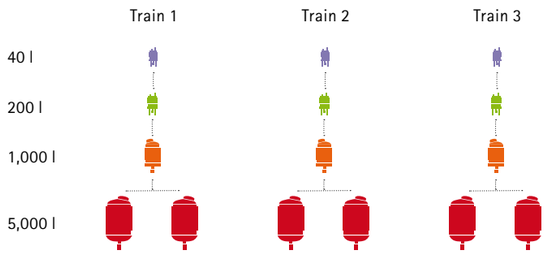
Tae Han Kim: Demanding projects, as for example the design and construction of large manufacturing plants, require trustworthy partners with specific know-how. Only experienced companies can meet the demands of "concurrent processing" which allow for a remarkable and valuable reduction of the overall project time.
Bioengineering did support us in all technical, quality and project management aspects to achieve Samsung's ambitious targets in time. The upstream part of the mammalian cell plant designed by Bioengineering meets all our customers' requirements and will therefore form part of Samsung's further success in the biopharmaceutical market.

Samsung core engineering and project team for Edison I

Kwang Jun Yoon (Purification) Woo Cheol Chae (Fill/Finish)
Ji Hye Kang (QC) Chung Woo Lee (Engineering)

Michael John Garvey (Cell Culture) Sun Jin Ko (Material Management) Sukhui Kim (Validation)
Bum Joon Kim (Validation) Min Tae Park (Process Development) Scott Mehltretter (QA)

Scope of supply at a glance



For Edison I, Samsung BioLogics selected engineering companies that demonstrated an in-depth knowledge of project execution, in addition to engineering expertise. Thus Bioengineering was the logical partner and supplier for the bioreactor systems.

Capacities and arrangement
The bioreactors are one of the key items of equipment for the entire production building. There are in total three bioreactor trains, arranged in a layout that allows transfers by gravity from seed to production systems. Each one of the three trains consist of cell culture bioreactors with working capacities of 40 l, 200 l, 1,000 l and twice 5,000 l. The total cell culture production capacity is 30,000 l.

Composition and cleaning
The three trains are arranged in one clean room on different levels. The 5,000 l bioreactors are suspended in the floor, while all others stand on the floor. The top section of the 5,000 l production bioreactor, including the gas mixing station, exhaust system and all liquid additions, is installed in the clean room area, while the bottom group is in a technical area together with the temperature control module. Sampling for the 5,000 l production bioreactor takes place from a separate clean room corridor. The entire bioreactor layout was designed by Bioengineering on a 3D basis and several design reviews were undertaken together with Samsung BioLogics.
All bioreactors are composed of the same equipment modules, such as temperature control units, gas mixing and aeration systems, exhaust modules, bottom groups, sampling systems and liquid addition lines with filter systems. The various measurement systems as temperature, aeration flow, stirrer speed, level, pressure, pH and DO were implemented for perfect process control and monitoring. The systems are fully automated to the highest industrial standards according to all conventional regulations.
The entire bioreactor is cleanable and sterilizable in place. Separate CIP operations for transfer lines are included from the different media hold or media preparation vessels, with a double block and bleed arrangement. Separate SIP operations are available for all transfer lines and other equipment modules. Transfers are carried out with overpressure from the sender vessel. Cultivation and pressure holding test operations are also included. All functions were developed by Bioengineering and described in FDS (Functional Design Specifications).
In addition to detailed engineering, procurement and manufacturing of the bioreactors, Bioengineering was responsible for the commissioning and qualification of the systems. The design review, factory acceptance test, site acceptance test and installation/operational verification were all executed with the strong support and supervision of Samsung BioLogics.

Qualifications
The documentation package supplied for operation and the validation of the bioreactors met the expectations of global regulatory authorities. The complete bioreactor system fulfills the requirements of the FDA, EMA and other global regulatory agencies. In June 2013, Samsung BioLogics started its first GMP manufacturing and the results thus far demonstrate high-quality execution.

Samsung BioLogics headquarters and production facilities in Songdo, Incheon

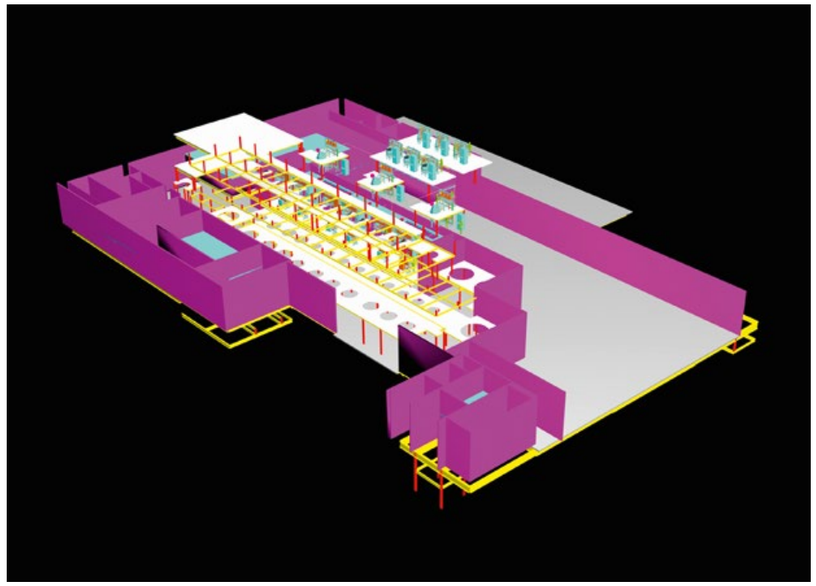
Building and plant engineering

Architectural model of the complete Edison I production building

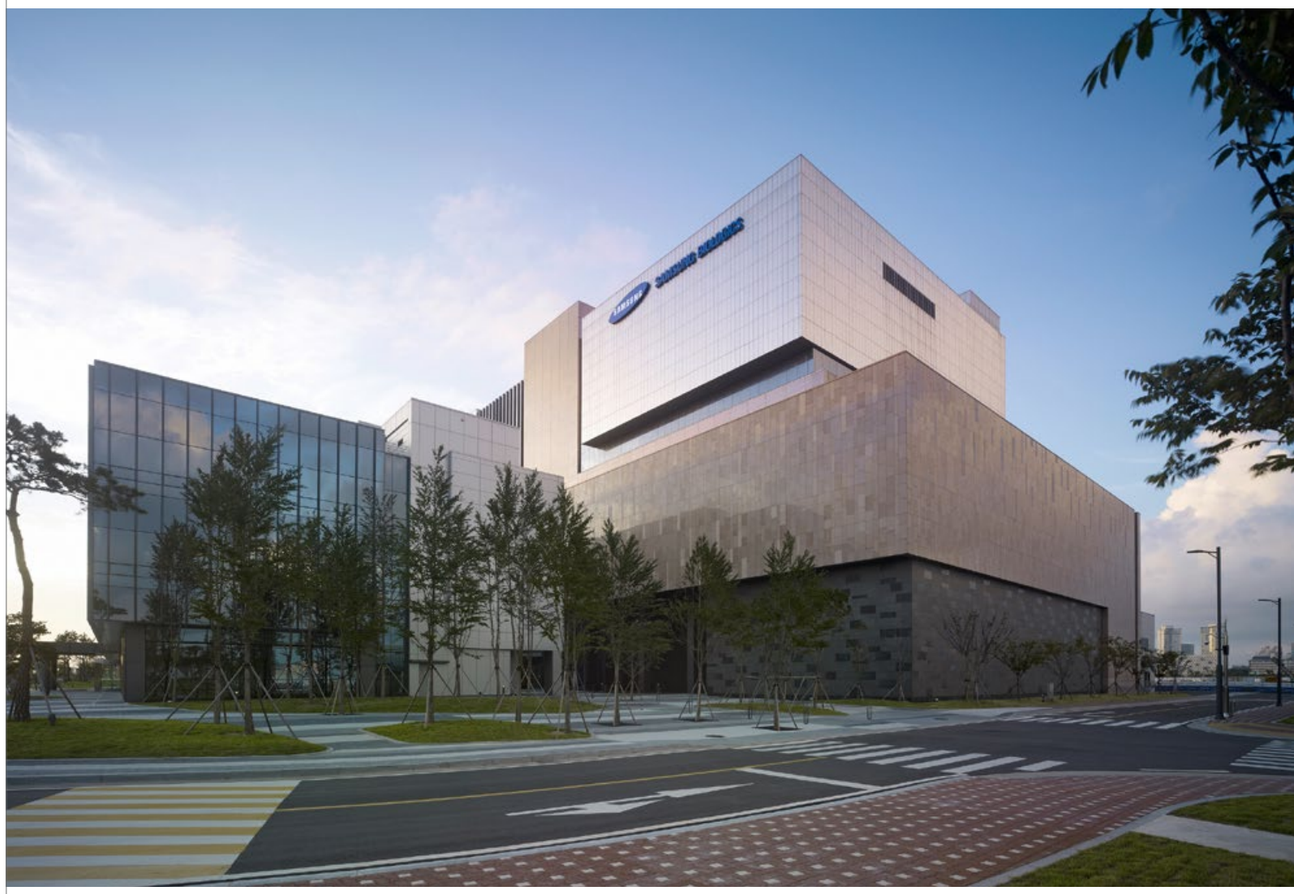
The Edison I production building comprises 8 floors with a total height of 55 m and offers a total floor space of 56,800 m^2. In addition to the production plant, the building also houses fully equipped QC labs, offices and a warehouse. The bioreactor trains are located between the 5^{th} and 7^{th} floor, fully integrated into the facility.

3D model view of the complete Edison I production building

The entire building shell, steel structures, hygienic piping and all packaging units were modeled using the 3D model software PDS. The bioreactors are shown in blue. The utilization of a common 3D model basis allowed for perfect and rapid integration of all the different units and pipe work. Complex interfaces between the processing units, different floor levels, pipe routing, steel structure and HVAC system can only be understood within a fully integrated 3D model. Extensive reviews during the 3D modeling phase were carried out as part of the design qualification (DQ).

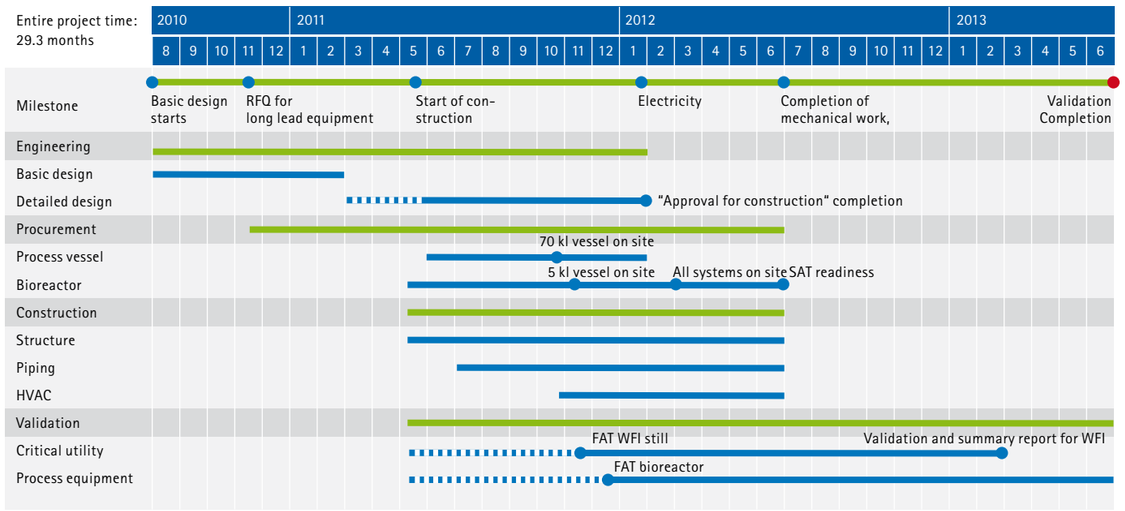


Final building



Execution excellence – concept

Within a limited time frame, all activities such as the engineering, procurement, construction and validation (EPCV) of the bioreactors were executed concurrently with all other EPCV activities related to building construction, process equipment, utilities and HVAC. The following graph shows the remarkable milestones of Edison I:



The timeline on pages 22/23, with site construction work in Korea and bioreactor manufacturing in Switzerland, gives you a good overview of all the parallel project phases.
To achieve successful project execution within this short time frame, Samsung BioLogics and Bioengineering deployed the following strategy:

Modular project design
A modular design approach was utilized to produce consistent and flexible units. All bioreactors are compiled of the same equipment modules (EM) with a defined functionality. The gas supply group, for example, is an equipment module with SIP, CIP and aeration functions. Further EMs developed for the project were exhaust modules, the harvest groups and liquid addition groups. Each equipment module was comprised of a description, a P&ID, 3D typical configuration and functional design specifications for automation. Given this library of standardized equipment modules, the bioreactors were simply assembled during detailed engineering. This approach reduces the time for each engineering discipline, for the qualification process and also offers substantial advantages to end user teams with regard to process safety and day-to-day operations.

Copy/paste units
All the bioreactor trains were completely identical and therefore duplications. This allowed for easy and fast copy and paste work with regard to all engineering documents and especially for the 3D model. The design of the bioreactor suite building was generous with regard to space and permitted placing of all units without any layout changes or adaptations to the building structure.

Validation plan ASTM-E2500-07
During the basic design phase, validation was planned and the ASTM-E2500-07 approach was selected as the validation strategy. By planning validation from a very early stage of the facility design, Samsung BioLogics was able to complete validation ahead of the projects, following the traditional validation schedule. This strategy utilized a systematic, efficient, and effective approach to verify that the bioreactor systems are fit for their intended use, have been properly installed and are operating correctly. The test results for the bioreactors from FAT and SAT and the commissioning of the installation/operational verification test documentation were some of the pivotal reasons for the success of the project.

Close collaboration
The project teams of Samsung BioLogics and Bioengineering established a close collaboration, based on daily communication and meetings. Samsung BioLogics followed the "System Owner Approach" and future operators of the bioreactors were also trained and empowered to be the technical system owners of the equipment during the EPCV phase. This ensured that technical knowledge for resolving possible issues with the bioreactors was always available. Thus the response time and cost were dramatically reduced. Project progress, missing information or open decisions were always transparent for all companies involved and closely monitored. Response times on both sides were short and the failure rate was minimized. The required decisions were always made directly in adherence to the time schedule. This allowed for optimal cooperation between the different partners and a perfect matching of all the activities.

Milestones

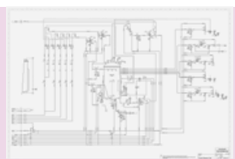

2

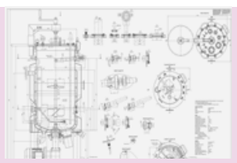
3

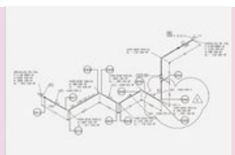

5

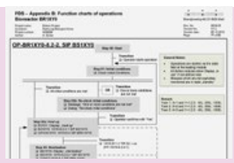

6

Engineering phase
5 months


9


10


12


14


15

Procurement phase
5 months


16a


16b

Manufacturing phase
7 months


18a


18b


19


20


21


22


24


25

Site construction phase
14 months

26

27a

27b

28a

28b

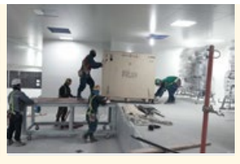
28c

Site installation phase
for bioreactors
8 months


32a


32b


33a

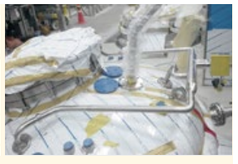

33b


33c


33d


33e

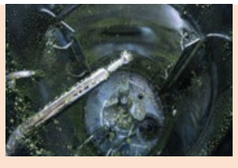

34a


34b

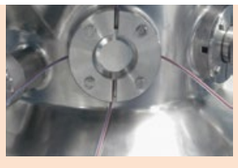
Validation phase for bioreactors
13 months


35

36a


36b


36c


36d


36e

38

Edison II

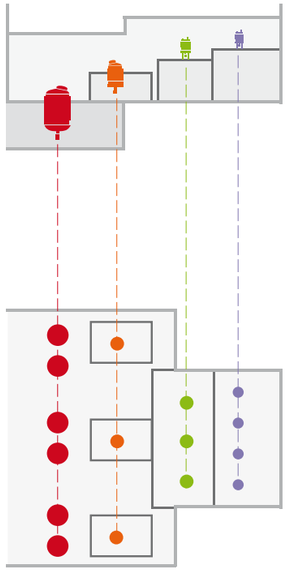
40

Images correspond with numbers in diagram on the translucent paper

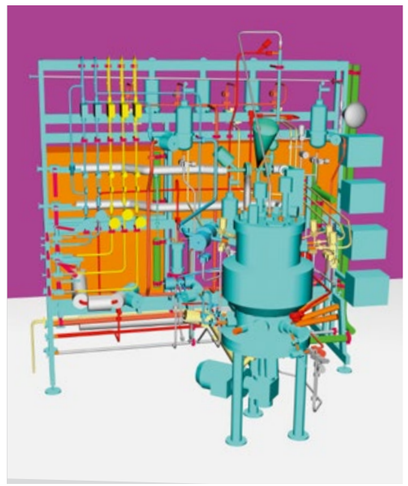
Execution excellence – timeline

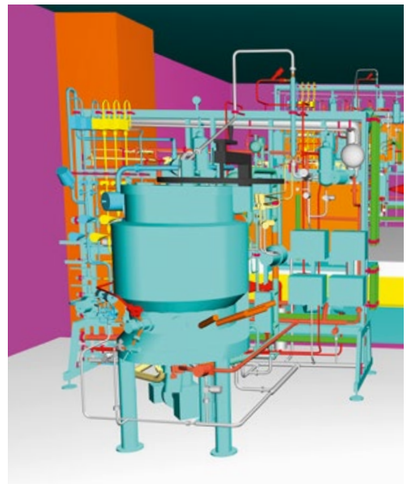
		Duration	In charge
Edison I			
	Milestones		
1	Establishment of Samsung BioLogics in Songdo, Korea		
2	Contract award and signing with Bioengineering		
3	Start of Edison I		
4	Delivery of bioreactors from Bioengineering EXW		
5	Mechanical completion of Edison I		
6	Final completion of Edison I		
7	Major validation activity completion for Edison I		
Engineering phase		5 months	Bioengineering
8	Kick-off meeting	2 days	
9	PID diagrams	40 days	
10	Vessel drawings	25 days	
11	Technical specifications	40 days	
12	3D modeling	80 days	
13	Electrical drawings	50 days	
14	Functional design specifications	65 days	
15	Design review	25 days	
Procurement phase		5 months	Bioengineering
16	Bioreactors	110 days	
17	Bulk material	60 days	
Manufacturing phase		7 months	Bioengineering
18	Spool manufacturing	35 days	
19	Vessel and skid positioning	15 days	
20	Skid assembly	45 days	
21	Instrumentation and automation hook-up	30 days	
22	PreFAT and commissioning	20 days	
23	FAT	20 days	
24	Packing	15 days	
25	Delivery to Korea	30 days	
Site construction phase		14 months	Samsung
26	Piling	65 days	
27	Steel structure	150 days	
28	Shell/interior	260 days	
29	Hygenic piping	150 days	
30	Black piping	260 days	
31	HVAC	175 days	
Site installation phase for bioreactors		8 months	Bioengineering
32	Installation of 5,000 l production bioreactor	10 days	
33	Bringing in, positioning/leveling seed bioreactors	20 days	
34	Reassembling and piping on site	60 days	Bioengineering
Validation phase for bioreactors		13 months	Bioengineering
35	Commissioning of bioreactors	25 days	
36	SAT bioreactors	80 days	
37	Qualification (IOV) of bioreactors	70 days	Samsung
38	Sterility test of bioreactors	60 days	
39	Enhanced qualification (PV) of bioreactors	125 days	
Edison II			
40	Contract award and signing with Bioengineering		

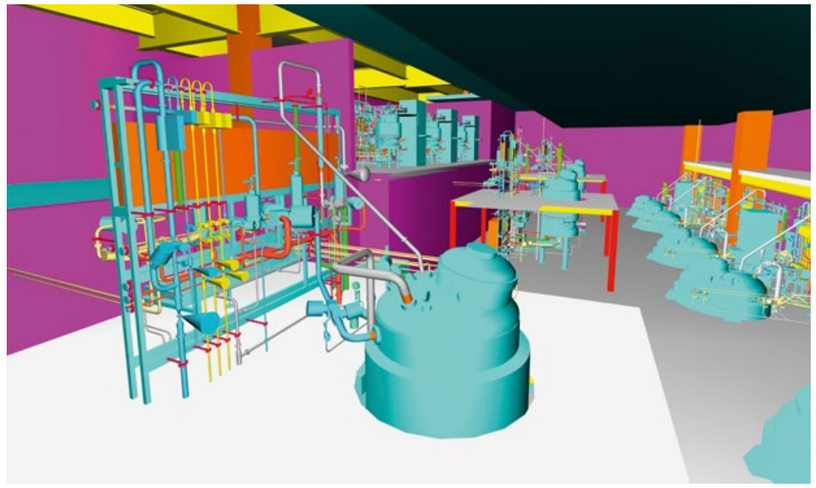
Numbers on diagram correspond to images below the translucent paper

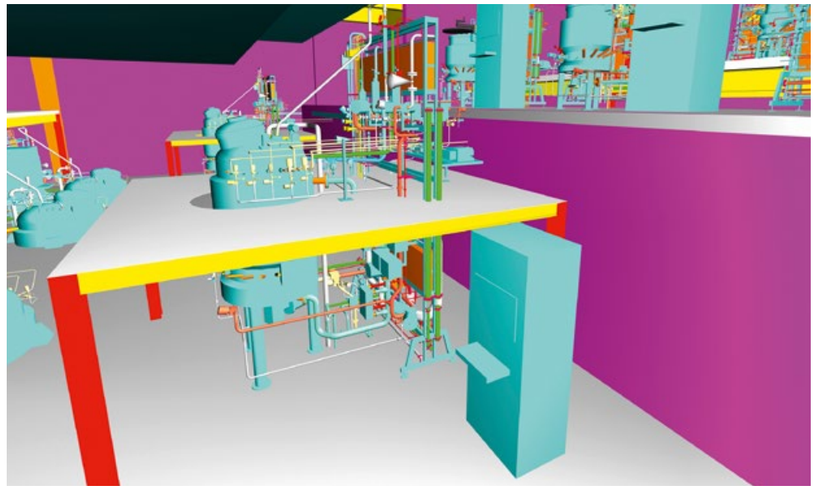


5,000 l fermenter
1,000 l fermenter
200 l fermenter
40 l fermenter









Left: 40 l (wv) bioreactor

The 40 l bioreactor is the first step in the cell cultivation train. Vessel ratios, mass flow rates and agitator designs were kept for all of the following bioreactor sizes to allow for an optimized scale-up of the process.

Vessel

Right: 200 l (wv) bioreactor

The next step in the bioreactor cascade is a 200 l (wv) vessel. Each of the bioreactor skids had its own battery limit to connect all the required utilities.

Vessel

1,000 l (wv) bioreactor, top view

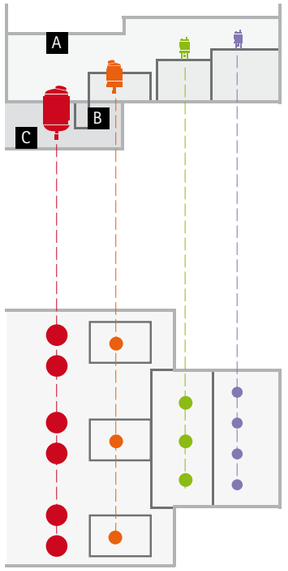
The 1,000 l bioreactor is the only vessel with a permanently installed platform. This picture shows the top view of the bioreactor with the gas mixing station on the left side and the exhaust group on the right side. Comparing the picture of the reactor with the 3D model gives you an impression of how detailed the planning was.

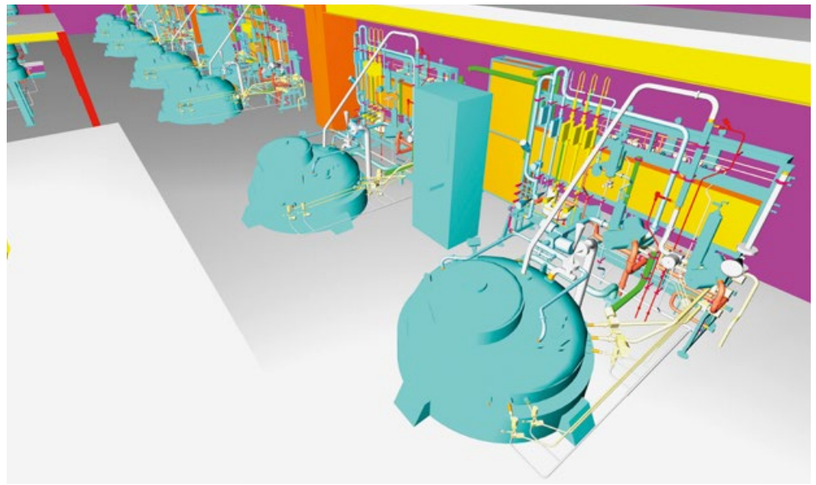
Vessel

1,000 l (wv) bioreactor, complete view

The inoculum transfers between the different bioreactors were in keeping with the "flow by gravity" principles. Therefore all the bioreactors are placed at different floor levels. This staircase-shaped design of the bioreactor suite allows for optimized and short transfer pipes and reduces the loss of product remaining in the pipes.

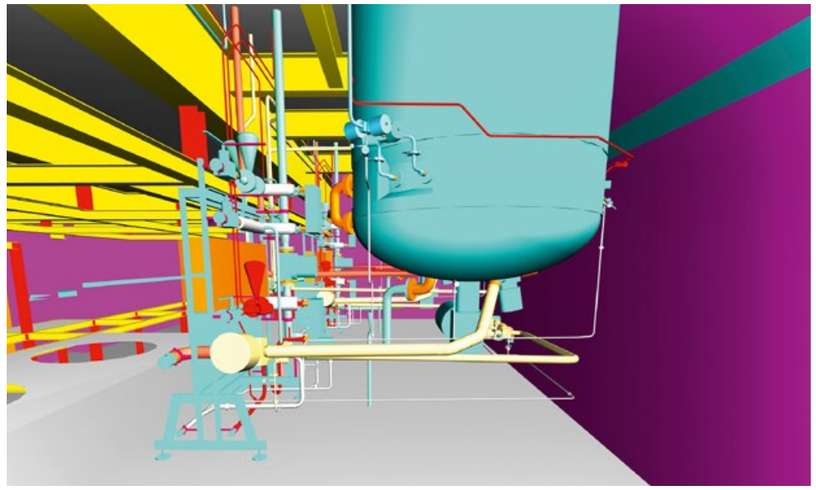
Vessel





5,000 l fermenter
1,000 l fermenter
200 l fermenter
40 l fermenter

View (see images)



5,000 l (wv) bioreactor, top view

The 5,000 l bioreactors where suspended from the steel structure of the building between the 5th and 6th floor. The 6th floor corresponds to the lowest level in the bioreactor suite and is a Class D clean room. The 5th floor is a non-controlled gray area in which the lower part of the bioreactor is situated.

View A
Vessel

Sampling corridor for 5,000 l (wv) bioreactor

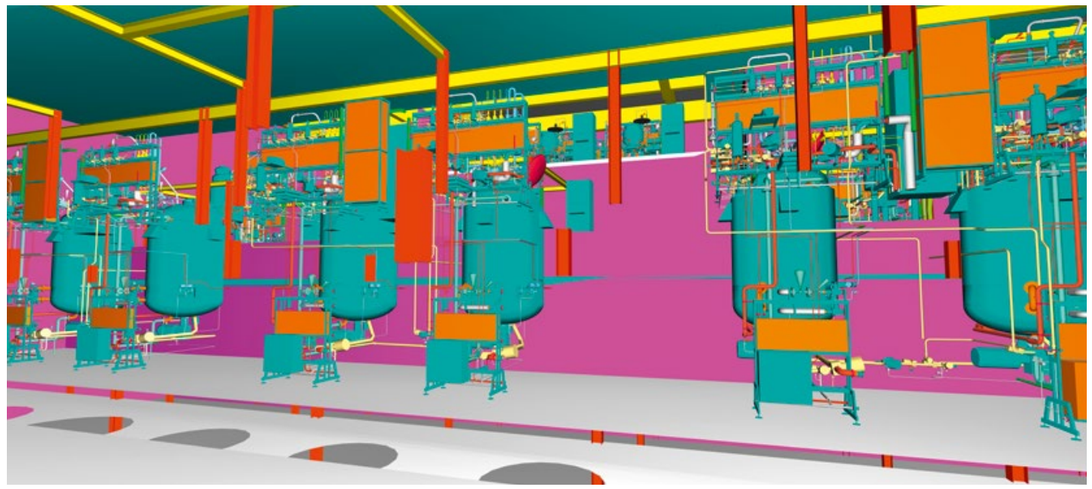
This is the view along the sampling corridor for all the 5,000 l bioreactors. The sampling corridor is reached directly from the bioreactor suite by a staircase and is below the 6th floor. Hygienic and controlled sampling is possible from this corridor, even if the lower part of the 5,000 l bioreactor is placed in a gray area.

View B
Vessel

5,000 l (wv) bioreactor, bottom view

Standardized heating circuits for all 5,000 l bioreactors were placed on the 5th floor. This technical area also contains the agitator system and the complete harvest manifolds toward the centrifuges. Having these parts in a technical area instead of a clean room is a substantial cost-reducing factor and an advantage for interventions by maintenance personnel (no gowning).

View C
Vessel



3D model view of all 5,000 l bioreactors, blinding out the 6th floor. One of the strengths of the project is the copy/paste effect of all units. Each train is exactly identical, which dramatically reduces the engineering effort. This copy and paste strategy not only simplifies the engineering process, it also has a time-saving effect in the qualification phase.

Left: 40 l (wv) bioreactor

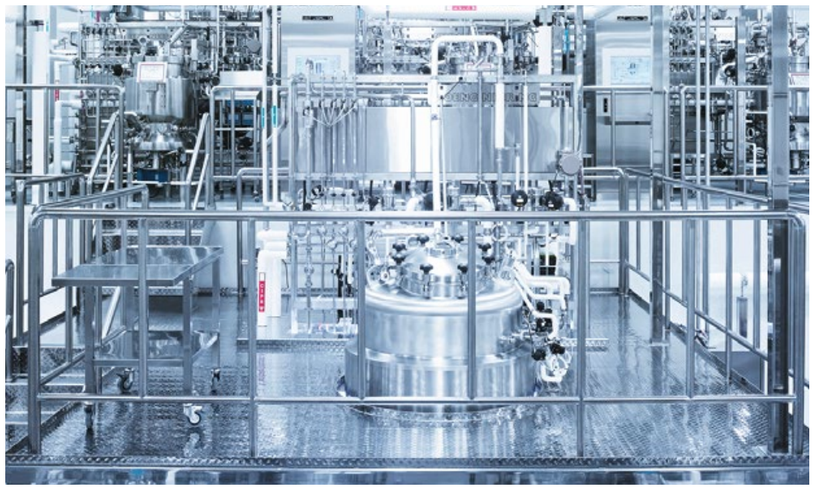
The open skid structure allows optimal space for maintenance, which was one of the key criteria during 3D modeling. Nevertheless the skids are compact to reduce the foot print in the clean room area.

Vessel

Right: 200 l (wv) bioreactor

The arrangements of the main groups of all bioreactors on the skids are in line with the same design guidelines. This and the library of 3D typicals from the standardized EMs, allowed for fast and uniform completion of the 3D modeling phase.

Vessel



1,000 l (wv) bioreactor, top view

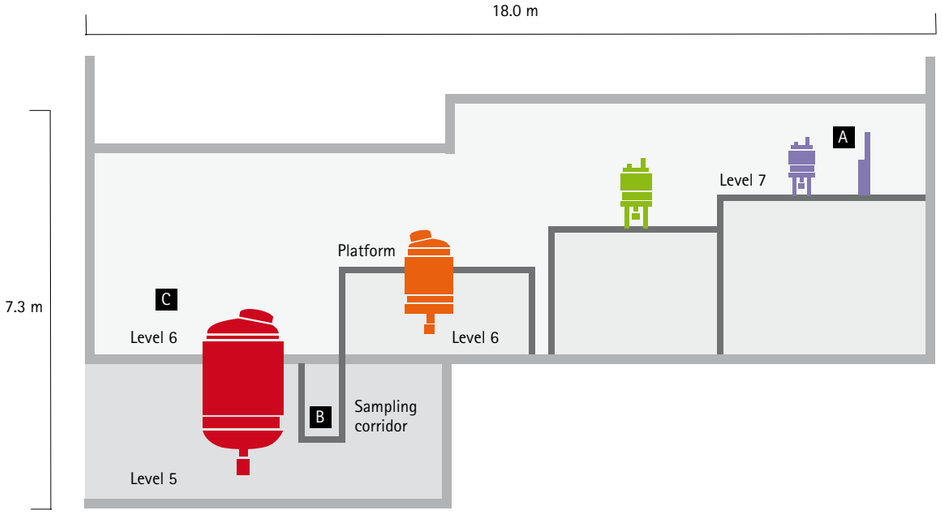
Each of the bioreactors had various addition lines for different nutrient additions and caustics. All of these addition lines are equipped with sterile liquid filters, which were located at the back of the skid. The transfer pipes were then aligned to give the operators enough space around the vessel. As a result, the space around the top of the vessel is tidy and clearly structured.

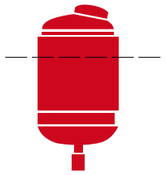
Vessel

5,000 l (wv) bioreactor, top view

As the vessel is fully integrated into the building structure, great attention was paid to the manufacturing and installation schedule of the largest vessels. All six 5,000 l bioreactors where manufactured within less than 5 months and installed into the steel frame structure of the building in November 2011. A stainless steel cover around the production vessel seals the vesel with the floor.

Vessel



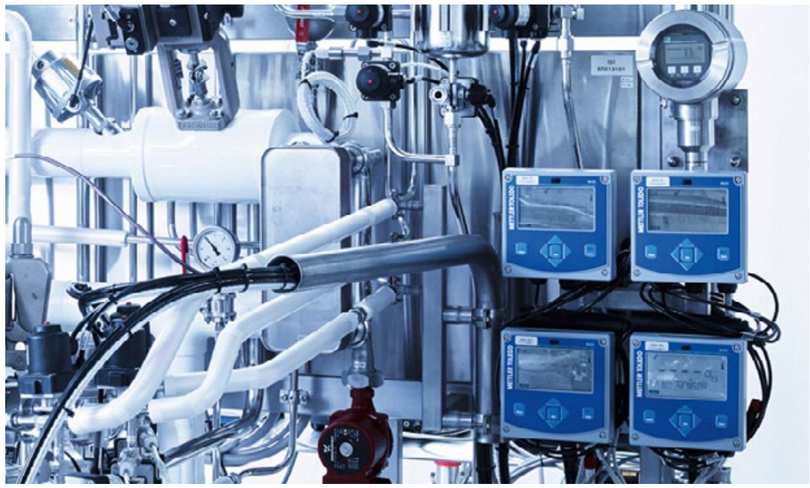


5,000 l fermenter with access from lower level 5 and upper level 6.

1,000 l fermenter with access from platform level 6.

200 l fermenter on separate intermediate floor between level 6 and 7.

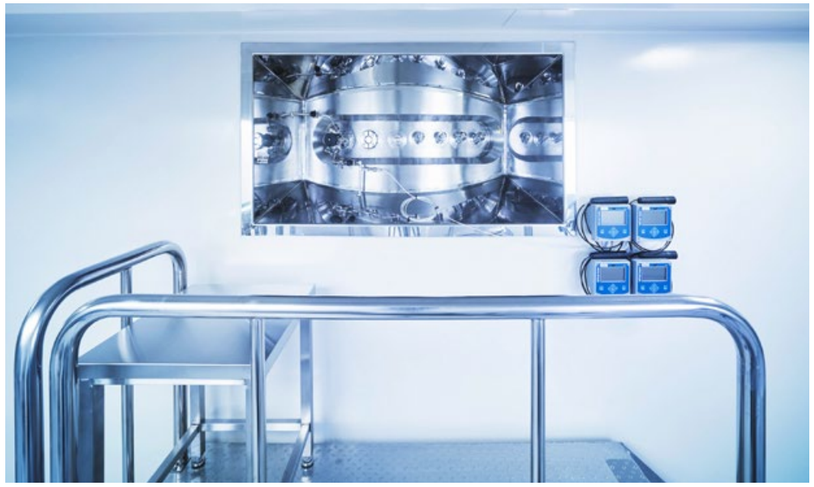
40 l fermenter on separate floor level 7.



Instrumentation

All bioreactors are equipped with different measuring and control loops for perfect cultivation control and process monitoring. Key process parameters such as pH, dO2 and temperature are designed as redundant systems. The bioreactors are fully automated to allow a reproducible and validatable process.

View A
Vessel



Sampling window

The production reactor is connected to the sampling corridor and sealed with a sampling window. In addition to the sampling valve, the pH and dO2 probes and transmitters are also located on the sampling corridor.

View B
Vessel

Bioreactor hall

The entire bioreactor hall is an impressive and state-of-the-art upstream facility. The bioreactors are neatly arranged and passages between the bioreactors are generously dimensioned for both staff and material flows.

View C
Vessel

Looking at a bright future

In 2013 Samsung BioLogics and Bioengineering AG signed the contract for the Edison II project.

Edison II is a remarkable extension of Samsung's mammalian cell cultivation capacity, with a total of 150'000 l. The project started in 2013 and will be completed in 2015. It consists of a total of 5 upstream trains. Each train has a seed bioreactor with a 120 l, 600 l and 3,000 l working volume. The production scale for each train is 2 x 15,000 l working volume. The project is designed for moderate titers of monoclonal antibodies. Plant 2 makes use of a similar overall basic design to plant 1 and will meet the regulatory compliance requirements of the US FDA, EMA and MFDS.

In addition to the upstream section, plant 2 has a competitive downstream section consisting of centrifugation, depth filtration and various chromatography steps. For the final drug product, fully equipped formulation areas are available with filling lines and a lyophilizer.

The modular project design for Edison I was successfully adapted to the extension project. The project speed and professional execution of Edison II are outstanding characteristics of this project. Experience and difficulties from the first project were consequently transformed into successful corrective and preventive actions for the new project. Plant 2 will exceed all expectations and assure Samsung BioLogics' position as one of the global contract manufacturers of our time.

Edison II
Extension of multiproduct biologics facility

Type	Facility for monoclonal antibodies and recombinant protein manufacturing
Cell culture capacity	150,000 l (10 x 15,000 l bioreactors)
Purification	Flexible moderate-titer processes, centrifuging, depth filtration, chromatography
Fill and finish	Liquid/lyo vials/PFS filling, 2 lines, 4 lyophilizers, labeling and packaging
Development stage	Commercial
Regulatory compliance	US FDA, EMA and Korean MFDS
Other	Overall design basis similar to plant 1
September 2013	Contract signing for bioreactor section
December 2014	Completion of mechanical work on site
December 2015	Ready for cGMP operation

고생 끝에 낙이 온다.

Go-saeng Ggeut-eh naki ohn-da.
At the end of hardship comes happiness.

Korean proverb