

# About OMICS Group

OMICS Group is an amalgamation of [Open Access Publications](#) and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 700+ online open access [scholarly journals](#) in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 1000+ [International conferences](#) annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.

# OMICS International Conferences

OMICS International is a pioneer and leading science event organizer, which publishes around 700+ open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 1000+ conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.

# The Review of Flexible Production Platforms for Pharma/Biopharmaceutical Processing

Maik W. Jornitz, President G-CON Manufacturing Inc.

# Agenda

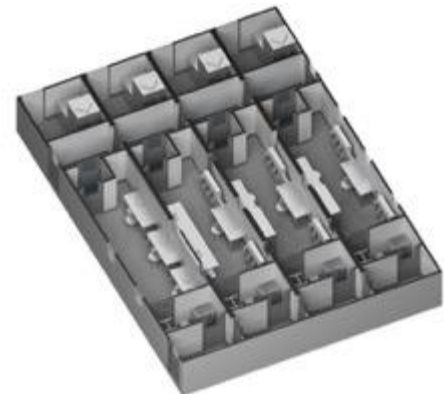
## Current Situation and Future Indicators

### Past & Current

- Facilities
- Processes

### Future

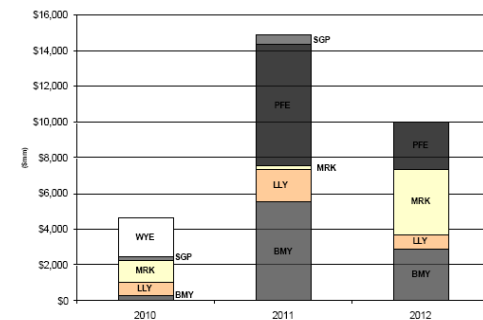
- Needs
- Possibilities
- Example cases



# Current Situations & Trends in the Industry

- Patent cliff for small molecules is reality and affects large molecule industry with coming biosimilars
- “Blockbuster” drug product era is changing into multi-product, targeted or personalized drug period
- Global expansion push to secure APIs and capture local markets
- Process volumes become lower and manufacturing requires to become more flexible for better facility and capacity utilization
- Single-use equipment lacks still the flexibility, when used in traditional facility lay-out

**\$30 Billion in Revenues Are At Risk For the US Pharmas in the 2010-2012 Cliff Period**

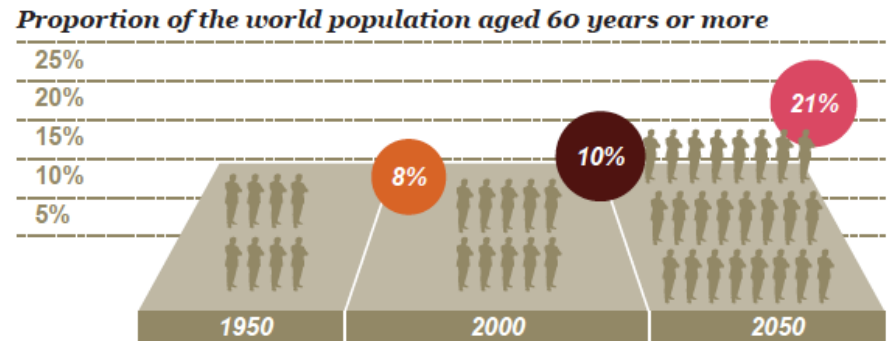


B. Ryan - September 2009 - page 8

Deutsche Bank

# Global Capacity Indicators

*Explosive population growth occurring in some areas versus declines in others, creating new competitive dynamics for clients, customers and talent*



Source: UN report World Population Ageing 1950-2050

## GDP of G7 and E7 countries at US\$ PPP

2009

\$29.0 trillion GDP



G7

(US, Japan, Germany, UK, France, Italy Canada)

Source: PwC Analysis

\$20.9 trillion GDP



E7

(China, India, Brazil, Russia, Indonesia, Mexico, Turkey)

\$69.3 trillion GDP



G7

(US, Japan, Germany, UK, France, Italy Canada)

2050

\$138.2 trillion GDP



E7

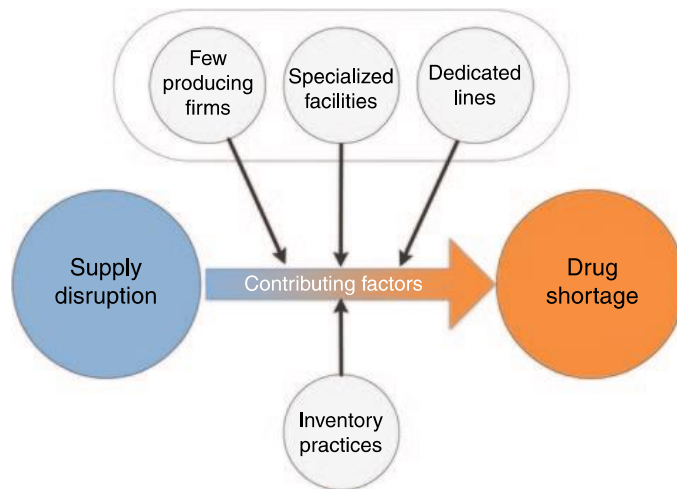
(China, India, Brazil, Russia, Indonesia, Mexico, Turkey)

*A rebalancing of the global economies.*

Courtesy: PwC, PDA Annual Meeting 2015

A rising middle class and aging population in the E7 countries, will demand appropriate healthcare from their governments, respectively the governments will want to produce medicinal products in their countries !

# Global Capacity Indicators, cont.



Source: J.Woodcock et al., nature publishing group, 2013

Drug shortage is still a major problem...in the U.S. !

From blockbuster to personalized medicine...  
how do we handle the processing,  
containment and logistics !





# Past & Current Options - Facilities



Traditional Hardwall



Offsite Built Modular



Modular - Stick Built



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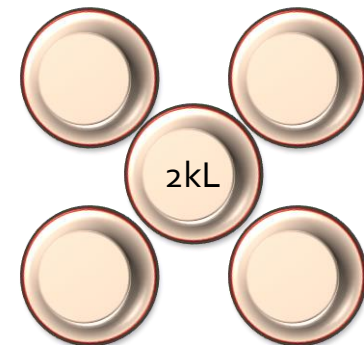
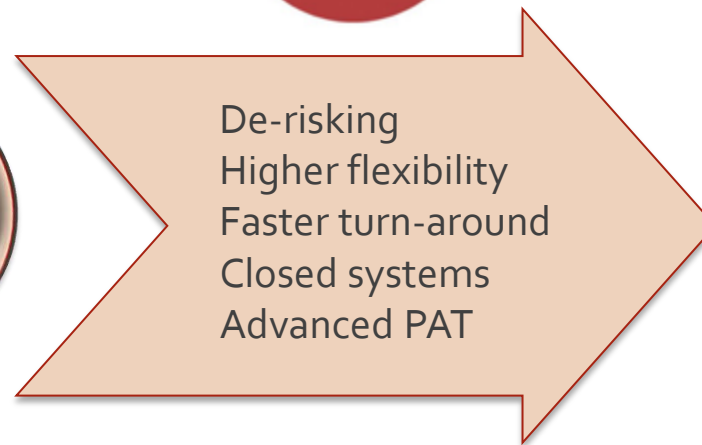
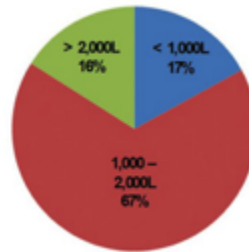
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- High CAPEX/higher OPEX
- Long time-to-run
- Product dedicated
- = • Inflexible/non-scalable
- Extensive qualification needs
- Difficult containment
- Difficult to clone



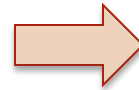
# Past & Current Processes

From large scale stainless steel to medium volume single-use



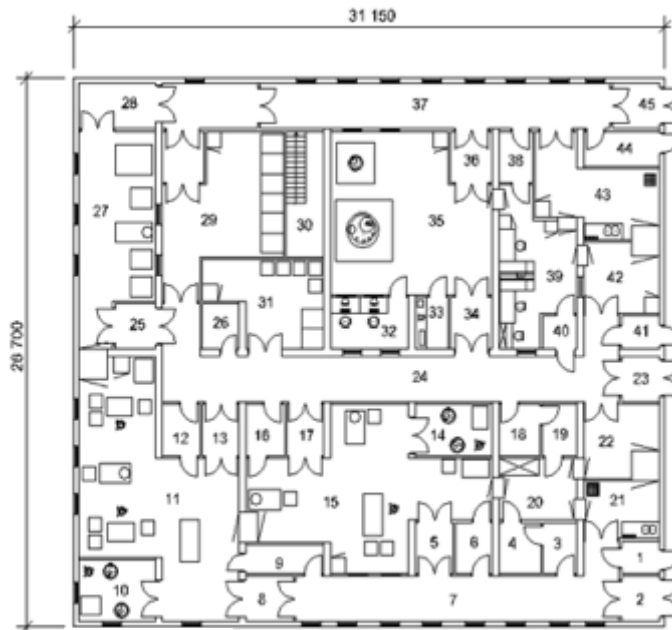
# Past & Current Processes

From Curtain to Isolator or RABS & from Vial to Needle to Needle to Vial

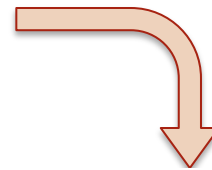


# The Benefits of SUT Voided

Single-use technology processes create flexibility & speed, but...



Courtesy Stedim



Courtesy G-CON Manufacturing



...is only as flexible as the surrounding infrastructure !

# New Facility & Process Needs Voiced

“Until now, **modular facilities have reproduced traditional architecture** with regard to embedding utilities piping and HVAC ducts in the interspace between the physical module limits and the suspended ceiling making refurbishment, if required, extremely complicated.

The **new approach is to segregate pre-assembled modules** into laboratory and utility modules, which are designed such that they permit even simpler and faster construction, qualification, validation and maintenance, respectively....”

Alain Pralong, VP New Product Introduction & Industrialization, GSK

“The pharmaceutical industry has been **so slow to adopt approaches** embraced by other industries, but I think the time is now,” FDA Commissioner Margaret Hamburg said during a tour of Vertex’s new continuous **manufacturing** line in South Boston, which would be one of the first such facilities to go into production if a new cystic-fibrosis drug is approved in mid-

2015  
Margaret Hamburg, FDA Commissioner

# Future - Possibilities

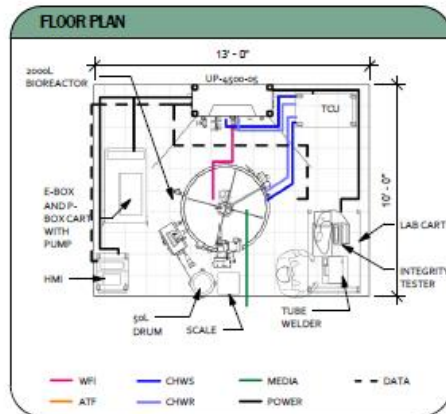
- ✓ Gaining full efficiency from single-use technology
- ✓ Autonomous cleanroom spaces
- ✓ Movable infrastructures
- ✓ Fast deployable, prefabricated unit operations
- ✓ Clonable in-country/for country facility platforms
- ✓ Processing spaces for new treatment options
- ✓ “Modular” cleanroom and facility designs





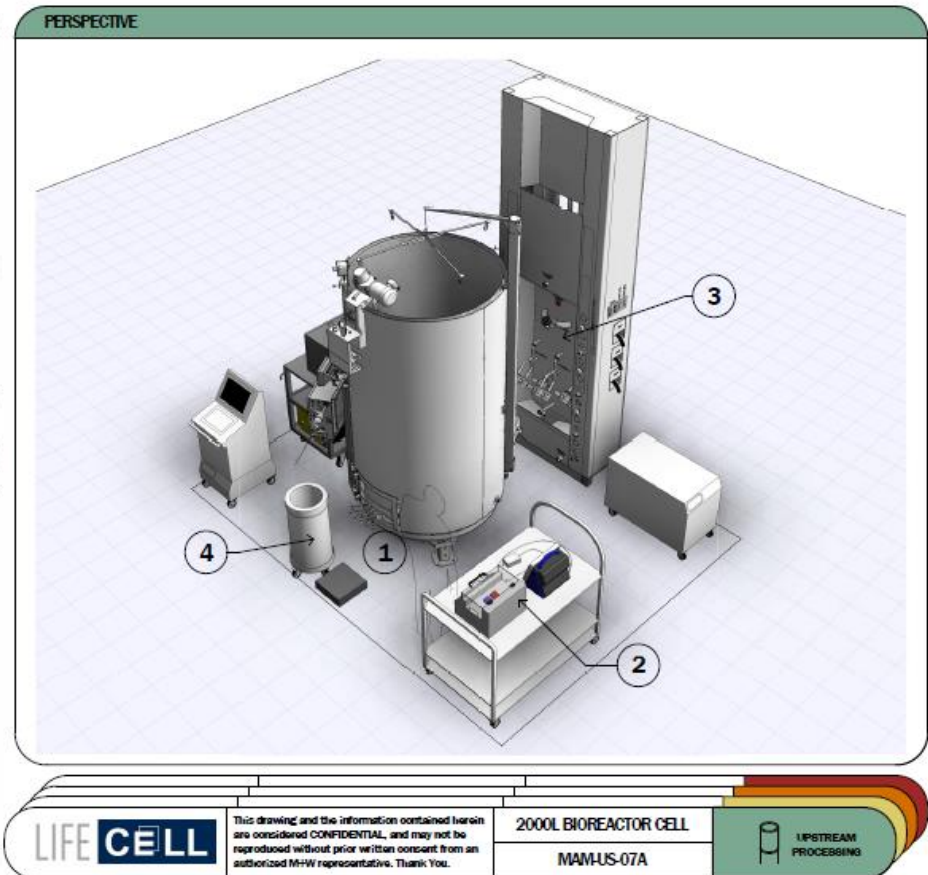
# Standardizing Our Thought & Design Process

Standardize process unit operations by design, which can then be integrated into a total manufacturing solution



**PROCESSING KEY**

WHAT YOU'LL NEED	PROCESS STEPS
X 3	① FOLLOW A PROCEDURAL TAKE-DOWN, CLEAN & SET-UP PROCESS. PERSONNEL WILL ENTER REQUIRED PARAMETER INFORMATION INTO THE HMI FOR THE REACTOR SYSTEM. ASSUMING PRE-SET FUNCTION ARE IN PLACE WITHIN THE SYSTEM, THE HMI WILL DIRECT TECHNICIANS TO INSERT & TEST THE SINGLE USE BAG AND ITS COMPONENTS PRIOR TO FILLING THE REACTOR.
X 4HRS	② PRE-MADE MEDIA TOTES ARE TRANSPORTED TO THE STATION. A TUBE WELDING PROCEDURE IS DONE TO CONNECT THE MEDIA TOTE TO THE REACTOR AND TO A PORTABLE PUMP TO TRANSFER THE MEDIA INTO THE BAG.
130V-UPS 300V 480V	③ WFI IS CONNECTED AT THE SINGLE USE BAG, THE BAG IS FILLED IN CONJUNCTION WITH THE MEDIA AND POWDERS TO INCREASE THE VOLUME OF THE SOLUTION.
WFI-5.5 LPM CHWS-5.5 LPM CHWR-5.5 LPM	④ AFTER THE REACTORS CYCLE HAS ENDED THE SOLUTION IS THEN FED INTO A PORTABLE DRUM, WEIGHED AND TRANSFERRED TO THE NEXT CELL FOR FURTHER PROCESSING.
CA - 5 BAR N <sub>2</sub> - 3 BAR O <sub>2</sub> - 3 BAR CO <sub>2</sub> - 3 BAR	

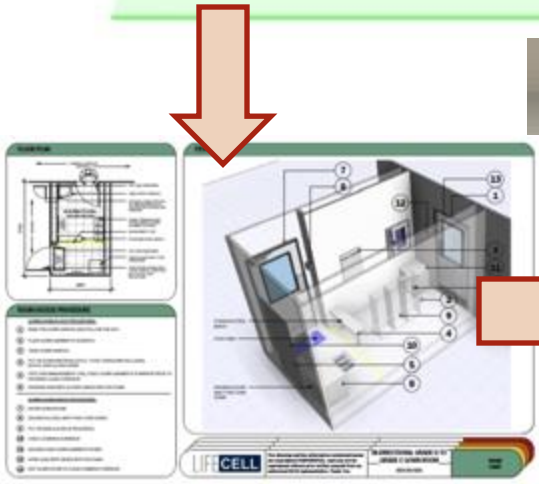
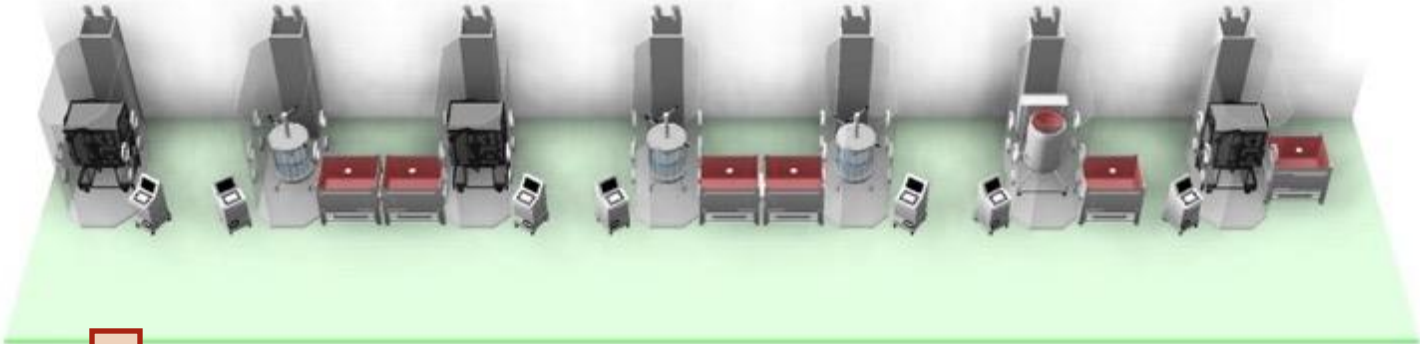


Courtesy: M+W

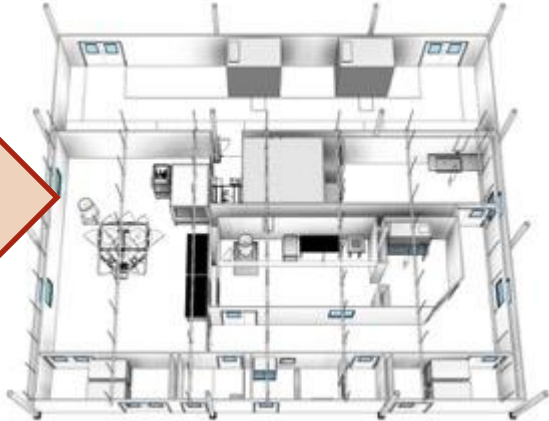


# Modular Process Unit Operation Designs

Develop modular and standardized design components ('building blocks'), which can then be integrated into a contextual solution.



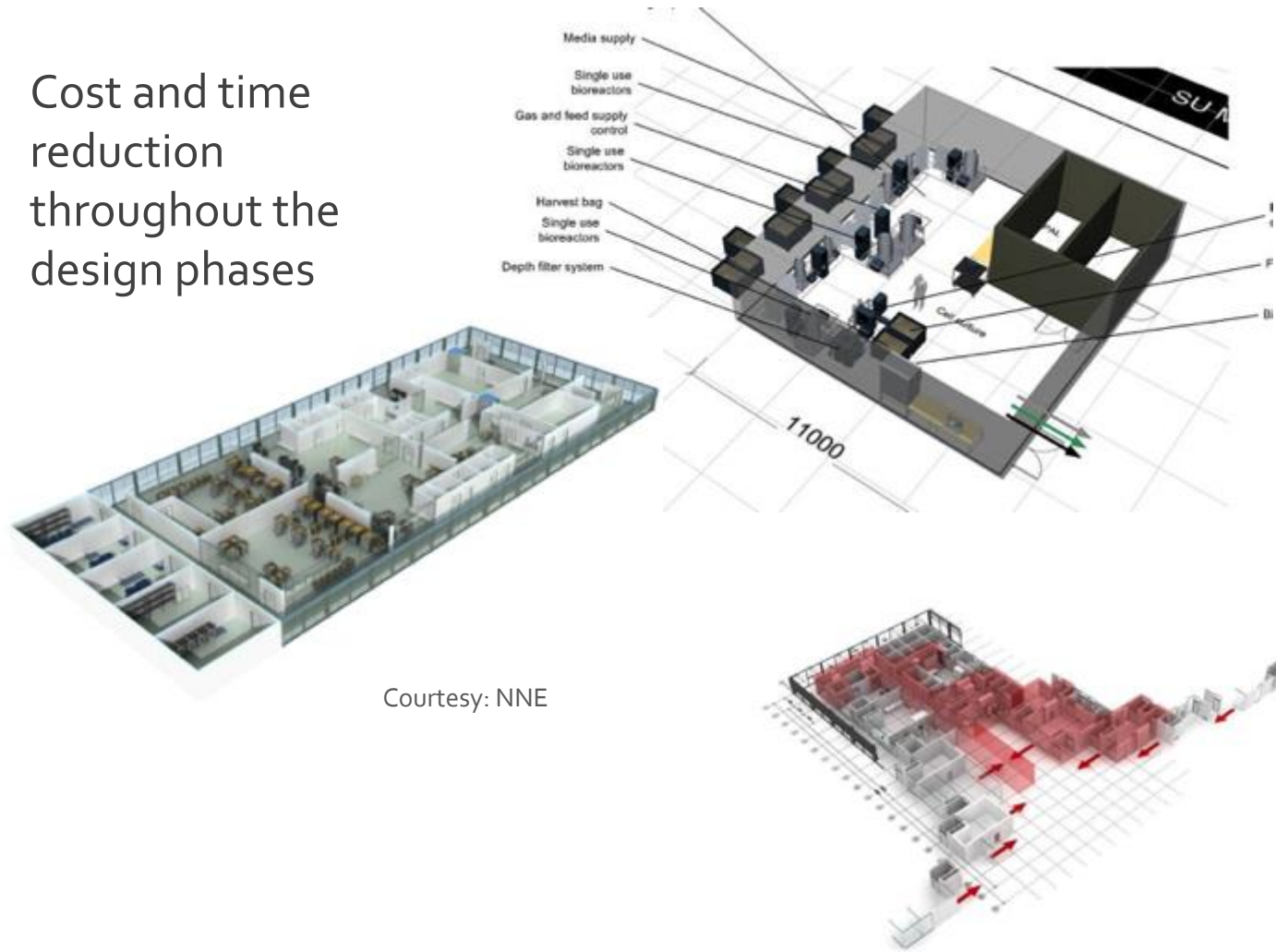
*LifeCells, standardized room designs, quality tested*



Courtesy: M+W

# Pre-designed Structures

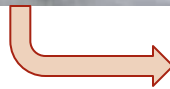
Cost and time reduction throughout the design phases



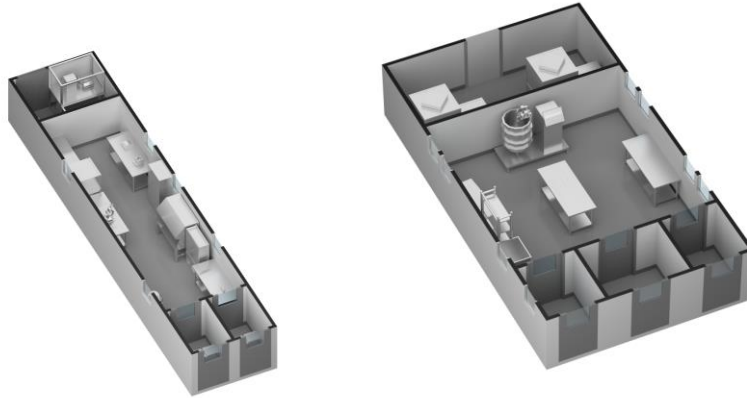
# Future Building & Cleanroom Infrastructure



Instead of building a shell around the process, the process is integrated into the shell



# Prefabricated Cleanrooms allow Faster Build



Built in 3 months

Off-site,  
prefabricated,  
turnkey cleanroom  
structures



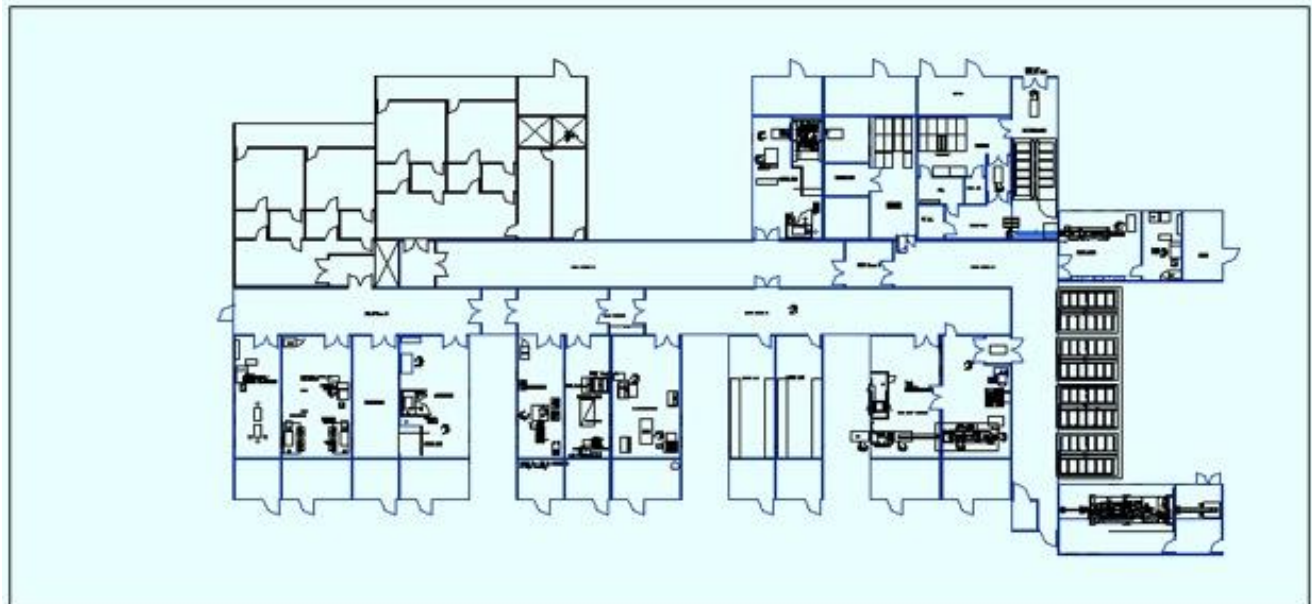
Built in 8 months



# New Cleanroom Concepts allow Facility Platforms



HVAC autonomous cleanroom units allow multi-product purposes



50,000 egg/day facility platform

# Facility Platforms allow Cloning



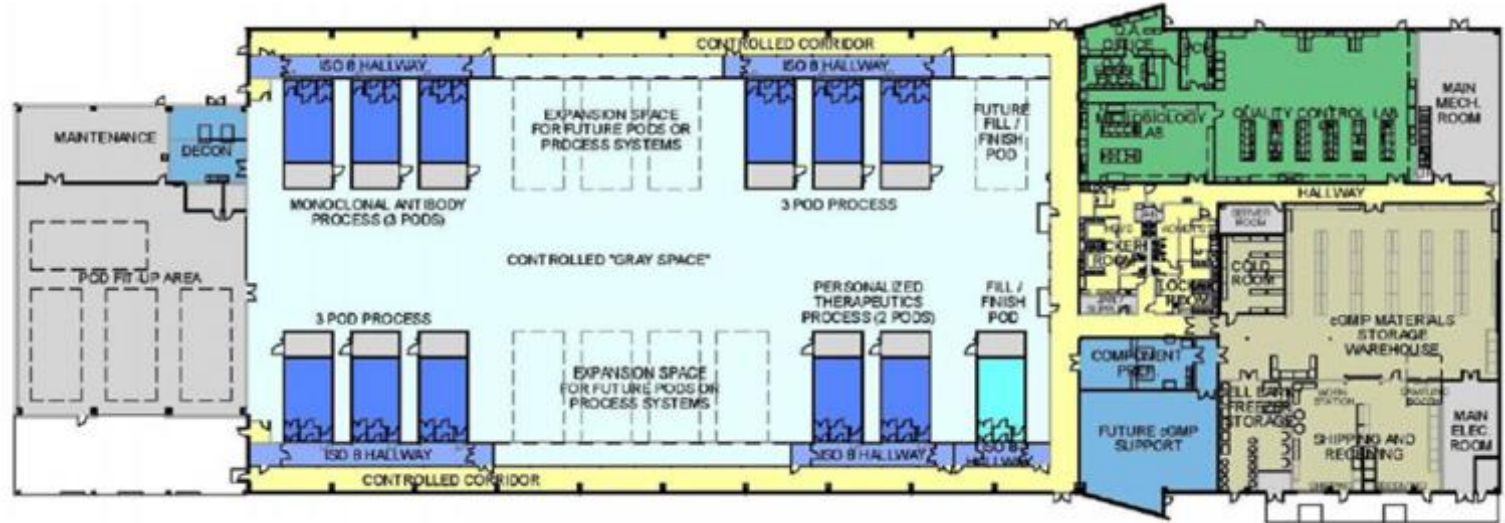
## Benefits:

- Known entity/process
- Known headaches
- Known qualification/validation
- Known filing needs





# New Segregation allows Multipurpose Sites



Courtesy: Kalon



## Benefits:

- Shared overheads
- Leasing possibilities
- Start-up clusters

# Conclusion

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- Current facility/process designs become obsolete and do not meet pressing industry requirements
- Multi-product/multi-purpose facilities are requested
- Facility deployment requires to be rapid and shortened by 2-3 years
- Single-use process technology supports new demands, but require the right cleanroom/facility infrastructure to be utilized to the fullest

*A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty.*

*Sir Winston Churchill*

Thank You !

Questions?

[mwjornitz@gconbio.com](mailto:mwjornitz@gconbio.com)



**Let us meet again..**

We welcome you all to our future conferences  
of OMICS International

**2<sup>nd</sup> International Conference and Expo  
on**

**Parenterals and Injectables**

**On**

**October 24-26, 2016 at Istanbul, Turkey**

[http://parenterals-  
injectables.pharmaceuticalconferences.com/](http://parenterals-injectables.pharmaceuticalconferences.com/)