Q4 2018

PODTalk

Leading Prefabricated Cleanroom Designs.

G-CON MANUFACTURING

IN THIS ISSUE

G-CON Manufacturing, Inc.

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4th Quarter Recap

FEATURED CONTENT

G-CON kicked off its planned expansion and shifted into high gear on the 8.8 acres it purchased in 2016. The building now under construction will provide an additional 72,000 square feet of manufacturing space at G-CON's corporate campus in College Station, TX, bringing the total square feet of production space to over 140,000.

G-CON has also hired its first international employee in Kilkenny, Ireland and now has representation in China and the Far East.

Through a collaboration with Asgard Cleanroom Systems, G-CON now has the ability to produce PODs at a new manufacturing site in Kilkenny, Ireland which will service the European region.

YEAR END CONFERENCES

With the topic of regenerative medicine continuing to gain interest, G-CON's exhibit at the Cell and Gene Therapy Bioprocessing and Commercialization Conference effectively presented PODs as the answer to global capacity needs and the need for speed to market. The conference highlighted key challenges facing the industry, including segregation and containment, flexibility, scalability and continuity as well as the need for innovative facility infrastructures. G-CON showed that PODs check all of those boxes.

G-CON also made its first appearance at the Biomanufacturing World Summit (BMWS) in San Diego, CA, teaming up with IPS to showcase our flagship product, iCON, and the newly released UBERcellFLEX product.

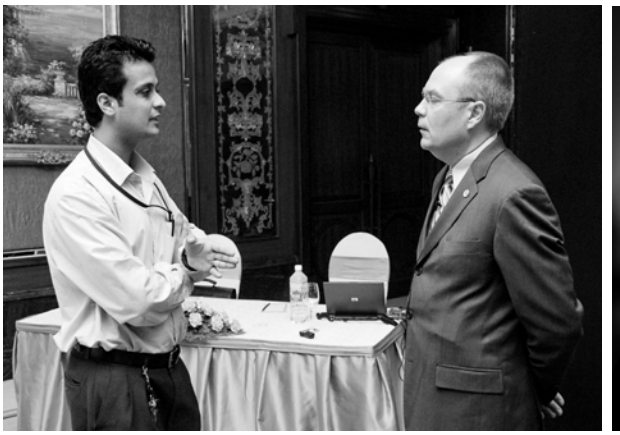
A LETTER FROM OUR CEO

Maik W. Jornitz
President and CEO

2018, a highly successful year for G-CON, comes to an end and I would like to first thank our customers for their business and trust in our innovative product platform. Once again, our team appreciates the highly positive feedback received from you about our novel technology, outstanding quality and the budget/delivery time robustness. This feedback has been shared with our entire organization, which instills pride and the motivation to go the extra mile. We look forward to future projects with you.

I also would like to thank our collaborators, collectively they have increased our manufacturing capacity, created additional distribution channels and expanded our product portfolio to support our customers. I am especially grateful to the Asgard team who invested into a new POD manufacturing facility in Ireland. This 120,000 sq. ft. facility will support our European customers, enhancing delivery speed and manufacturing reach.

I would like to express my appreciation also to our board members for their continued support; their belief in our company, team and products has not wavered since our inception. Our board has enabled the doubling of our manufacturing capacity at our headquarters in College Station, TX. This additional manufacturing capacity will enable us to meet heightened demand for our PODs for the foreseeable future.



Finally, I am indebted to the G-CON team. Their diligence and motivation in supporting our customers and ultimately patients is a key to our success. I could not wish for a better team.

Having said this, we continue striving for improvement. We firmly believe we can bring new products and services even faster to our industry. Such is needed as new therapies and medicinal developments require faster capacity build-up and scaling.

Some key elements of our business in 2018 are worth noting:

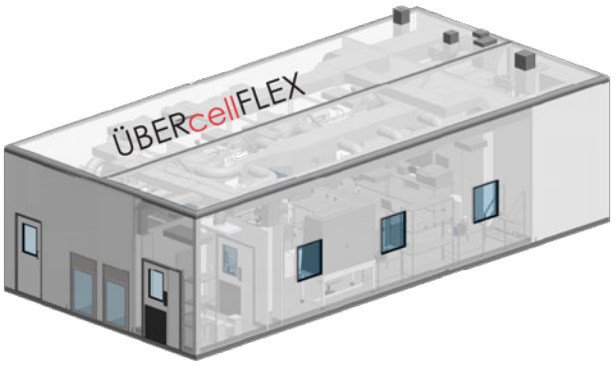
- We established ourselves as a leader in cell and gene therapy applications. Our PODs provide a scalable solutions with robust containment for these applications with unparalleled speed.
- Together with IPS, we launched our second iCON platform. After the UBERbioFLEX solution for antibodies, we now provide a cell therapy turnkey facility platform, called UBERcellFLEX.
- We have added close to 200,000 sq. ft. of new manufacturing space to our existing capacities.
- We strengthened our automation, engineering, project management and quality functions with added personnel and capabilities.

As we always state and firmly believe in, your success is our success and we look forward to supporting your success to the fullest! The entire G-CON team wishes you and your loved ones a blessed and peaceful holiday season!

IN THE NEWS

Pall Corporation and G-CON Manufacturing Collaborate to Deliver Custom Scalable Turnkey PODs® for Flexible Continuous Bioprocess and Viral Vector Facility Solutions
September 2018

G-CON Manufacturing and Pall Corporation, a global leader in filtration, separation and purification, collaborate to bring turnkey continuous bioprocess or viral vector production facility solutions to the industry. G-CON PODs will be customized with advanced Pall Biotech bioprocess equipment, including automation and utility supplies; these will be predesigned into the G-CON cleanroom units for scalable deployment.



IPS and G-CON Launch iCON Cell Therapy Facility Platform
July 2018

Following up on the launch of the iCON Turnkey Facility Platform for a mAb manufacturing facility late last year, IPS and G-CON successfully designed and delivered the first ÜBERcellFLEX PODs for the manufacturing of autologous cell therapies. The iCON solution provides a pre-fabricated modular cleanroom infrastructure for the drug manufacturers' requirements for both clinical and commercial manufacture of critical therapies.

G-CON Manufacturing Receives the UL Listed Mark as a UL508A Panel Shop
July 2018

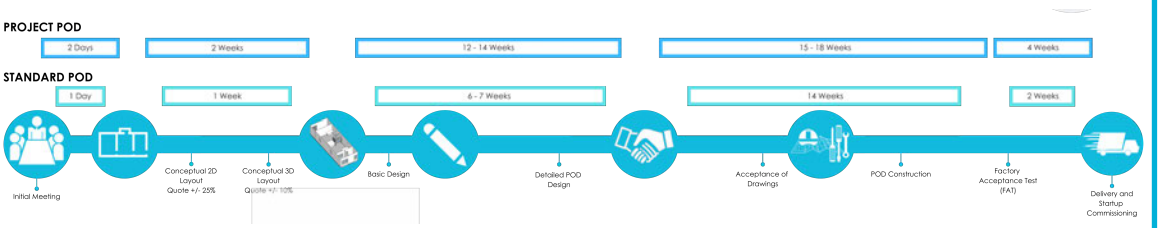
After testing G-CON's general purpose industrial control panels, UL (a nationally recognized, independent product safety certification organization), determined that G-CON's ability to design and build the same meets UL's standards. As such, G-CON is now a certified UL508A Panel Shop by UL Listing standards. The UL508A certification allows G-CON to independently design and produce UL508A labeled panels certified to meet a known safety standard.

G-CON Receives Brazos Valley Economic Development Corporation's Launch Award
July 2018

G-CON was honored with the Brazos Valley Economic Development Corporation's Launch Award. The Launch Award honors independent, privately-held corporations, proprietorships or partnerships and recognizes the company's scale of operations since startup toward second-stage growth. G-CON received this award by demonstrating a distinguished industry achievement through PODs and transforming its local region's marketplace in advanced manufacturing, biotechnology and engineering.

TECHNICALLY SPEAKING

The Importance of Reduced and Predictable Project Timelines



Dennis Powers
Vice President of Business Development & Sales Engineering

Introduction

Reducing project schedules and completing facility projects on time has never been more important to our industry than it is today. It is critical that drug manufacturers have the capability of and capacity for producing therapies and treatments that are needed by patients around the world. With the spotlight on the new cell and gene therapies that are being launched, and their effectiveness for curing life threatening diseases, the importance of well-controlled project timelines using pre-fabricated modular facility solutions continues to grow.

The Impact of Project Timelines

Historically, most drug manufacturers have followed a traditional facility construction approach with extended project timelines, high onsite complexity, and risks. Very few of the facilities built using this approach were completed on time to their planned schedule and it was not uncommon for a new facility project to take up to 5 years from start to finish. Because of the duration of project schedules and the unpredictability of traditional on-site construction, drug manufacturers have had to make large capital investments in new facilities long before they required the capacity for their drug products. This has posed significant financial risk to the companies under the following scenarios:

- A facility built for a drug product that failed in clinical trials and/or did not get regulatory approval
- A facility delayed in start-up that could not commercially manufacture a new drug product upon regulatory approval
- A facility which was oversized and underutilized for producing a drug product that did not achieve the expected market acceptance
- A facility which was undersized and not capable of meeting the market demand for a drug product.

The Problem with Traditional Facility Schedules

There are many reasons for lengthy schedules and why they get delayed during the design, construction, and commissioning phases of a project. Because most facilities in our industry have been stick-built, each one has been a unique or custom design based on the manufacturers' requirements, but also on the A&E firm's experience, design preferences, and desire to differentiate their work. This non-standardized approach requires a significant upfront engineering design effort with multiple stage gates for design reviews and approvals before moving to the next phase.

Traditional stick-built facilities require sequential construction phases where the building shell is first erected, followed by building core and utilities, and finally the critical cleanroom and process infrastructure. This requires the continual planning, coordination, and interaction of multiple sub-contractors and services at the construction site. Due to the complexity there is often a domino effect of construction delays if tasks are not started or completed on time due to permitting issues, material availability, labor shortages, or weather.

The Benefits of a Pre-Fabricated Modular Solution

PODs represent an innovative pre-fabricated modular cleanroom solution that can be effective in avoiding the extended project schedules, delays, and many other issues experienced with traditional construction. The off-site fabrication of the PODs allows for parallel construction activities of both the cleanroom infrastructure and shell building/core which provides a more compressed project timeline. And because the PODs are fabricated in a well-controlled factory environment by an experienced labor force, the risk of schedule delays as well as the number of on-site contractors, staging areas, safety issues, and overall project liability can be significantly reduced.

The end result is a shorter and more predictable project timeline that can help drug manufacturers produce the required capacity when they need it. The prefabricated approach also mitigates manufacturers' financial risks by allowing them to delay their capital investment until months before the capacity is required or until the product is further along in the clinical trial process and with a higher probability for regulatory approval. The pre-fabricated modular approach can help companies prevent the potential loss of millions of dollars in revenue as well as prevent the wasting of millions of dollars in capital to build a facility that cannot be used as planned.

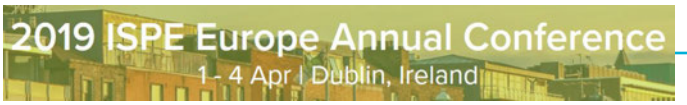
UPCOMING EVENTS

PHACILITATE: LEADERS WORLD

WORLD STEM CELL SUMMIT

Hyatt Regency Miami, FL
January 22 - 25, 2019
Exhibiting Booth #416

San Francisco, CA
February 7 - 9, 2019
Exhibiting Booth #TBA



Dublin, Ireland
April 1 - 4, 2019
Exhibiting Booth #TBA

INTERPHEX

New York, NY
Javits Center
April 2 - 4, 2019
Exhibiting Booth #2429

FEATURED COLLABORATORS

Through relationships with our collaborating entities, we can provide turnkey solutions for our customers. G-CON values and thanks our collaborators.

AMUR Equipment Finance

ASGARD SUPERIOR CLEANROOM SOLUTIONS

BUTLER

ips

MilliporeSigma

PALL

SPAN CONSTRUCTION & ENGINEERING, INC.

VALSOURCE

SPOTLIGHT

ON THE ROAD AGAIN... MORE PODs MAKE WAY TO PFIZER

Enhancing and Expanding

Further expanding its Portable, Continuous, Miniature, and Modular (PCMM) collaboration with Pfizer and GEA, G-CON completed the design and construction of additional PODs for integration into the existing POD-based Oral Solid Dosage line. With installation of GEA Tablet Coating equipment in PODs now complete, PODs shipped out from College Station, TX on Nov 26th. The new PODs will provide tablet coating capability in the existing line at Pfizer's site in Groton, CT.

Seamless Integration

The engineering design and closely coordinated efforts between Pfizer, GCON and GEA allowed for a seamless integration of GEA's leading-edge ConsiGma™ Continuous Tablet Coater equipment into the PODs at G-CON's facility. The ConsiGma™ coater from GEA is a high performance tablet coating technology that gently and accurately deposits controlled amounts of coating materials on tablets — even if they are extremely hygroscopic or friable. Designed specifically to be an integral part of the ConsiGma™ continuous tableting lines, the ConsiGma™ coater is able to process small quantities of tablets at very high rates, offering improved heat and mass transfer.

The additional PODs will occupy approximately 700 square feet of area adjacent to the existing PCMM PODs and will include a film coating process area, dedicated airlocks for personnel and material, and an integrated technical space for the G-CON and GEA mechanical systems.

HIGHLIGHT:

Integrating the equipment in the PODs and testing prior to delivery further reduces the time and complexity of installation at the Groton site and minimizes the downtime of Pfizer's current operations.

G-CON MANAGEMENT TEAM

Maik W. Jornitz
President and CEO

Paul Moore
Chief Financial Officer

Sid Backstrom
VP of Business Management

Dennis Powers
VP of Business Development
and Sales Engineering

Blake Williams
VP of Manufacturing

Tom Ronat
Director of Quality Assurance

Mark Taylor
Director of Engineering
and Project Management

Brittany Berryman
Director of Marketing

Have a project to discuss?

Email us at sales@gconbio.com

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