Engineering Design & Project Delivery for the Pharmaceutical Industry.

Welcome to our September newsletter. This issue contains an overview of ASTM E2500 VS Commissioning & Qualification. It also gives a brief overview of the 3D Mechanical Design and its advantages. We have also published an article in Engineers Ireland Journal about the Impacts and requirements of the Pressure Systems Regulation Act. As we continue to grow, we would like to introduce our new team members. For more information on our current projects and to sign up to our email newsletter, please go onto our website www.bpe.ie. We do hope you enjoy this newsletter and thank you for your continued support. Any feedback or comments you may have would be highly appreciated.

3D Mechanical Design

Within BioPharma, we focus on 3D design values, principles and visualization. Our focus is to utilize the multi-faceted nature of 3D design providing an insight into design working methods through information gathering for individual projects.

Mechanical 3D models using CAD tools brings life and transparency into the design goals with respect to clash detection, clearance, aesthetics, tolerances and aspects that help communicate design ideas more effectively. Using 3D design modelling greatly improves design quality as it is a more complete process than 2D design.

Communication of design intent is vastly improved by using CAD 3D modelling. In the past, non-technical people involved in a project often had to wait until a design was constructed before they could truly understand a design. Today modelling can be used to generate walkthroughs and pictorial views, as well as traditional projections, the design intent can clearly be seen by anyone willing to look. Also, a design engineer may want to introduce a value-added design to an existing part, but the first manufacturer of the part may not be willing to release their internal CAD files for proprietary reasons.

The process of 3D modelling overcomes these problems by allowing the creation of a CAD model by scanning the existing object.

Advantages of 3D Mechanical Cad Design:

- Efficient.
- Accurate.
- Visually identical to finished product.
- Communicates well with other disciplines. (i.e. electrical, HVAC etc.)
- Cost Saving.
- MTO's for pipe, fittings, steel & valves.
- Minimises errors.
- Clash detection capabilities.
- Quality.
- Useful for making presentations, brochures and manufacturing.
- Generates 2D & GA drawings instantly.

Please contact Billy Garrett for more detailed information on this topic and to find out what importance it can play in development of your new project on bgarrett@biopharma.ie or read more on www.bpe.ie.

ASTM E2500 Vs. Commissioning & Qualification

The American Society for Testing and Materials (ASTM) norm ASTM E2500, "Specification, Design, and Verification of Pharmaceutical and Bio-pharmaceutical Manufacturing Systems and Equipment" is one of the requirements referred to when it comes to Qualification and Validation. This standard has been developed with input from industry and with the support of the FDA, EMEA and GAMP and was approved in May 2007, published in July 2007 and revised in 2012 (with no significant change).

This Baseline Guide, Volume 5: Commissioning & Qualification, published in 2001, provides advice and guidance that may be applied to all types of facilities, utilities, and equipment found in the healthcare industry. The Guide has incorporated comments from industry representatives from all areas and disciplines, FDA Field Investigators, and personnel from the FDA’s Center for Drug Evaluation and Research (CDER).

The ISPE has now issued an Appendix to its Baseline Guide to assist companies in transitioning from traditional impact assessment based qualification approaches to ICH Q9 QRM based approaches found in ASTM E2500 and the ISPE ESE Guide. This Appendix is entitled ‘ISPE Guide: Science- and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment’. ISPE Baseline Guide

According to the 2001 issue of the ISPE Baseline Guide, Systems are defined and impact assessed, either by the impact of operating, controlling, alarming, and failure conditions on product quality. Impact assessments occur after design development and focus on systems and components. Those Systems found to have a Direct Product Impact are Qualified and Commissioned. All other Indirect and No Impact systems are Commissioned only.

Below is universally accepted model popularly known as V model for validation as outlined in the ISPE Baseline Guide.

ASTM E2500 states that verification is “A systematic approach to prove that Critical Elements, acting singly or in combination, are fit for intended use, have been properly installed, and are operating correctly”. This verification would normally be documented in IQ, OQ, and PQ documents. The extent of verification and the level of detail of documentation is dependent on the risks as outlined above.

The following is a diagrammatic representation of the ASTM Standard approach:

We would like to welcome the following new team members to BioPharma Engineering as we continue to strengthen the team and add to our capabilities.

Daniel O’Regan – Process Engineer

Daniel is an experienced Lead Process Engineer with over six years of industrial experience. Daniel qualified with B.Eng (Hons) in Chemical & Process Engineering from Cork Institute of Technology and spent a number of years as a Lead Process Engineer working in GSK, Pfizer, SAPC, AstraZeneca and many more. Daniel’s skills and experience spreads across multiple sectors, including Pharmaceutical, Heavy Chemicals and Waste to Energy design projects. Currently Daniel is working on several BioPharma projects for DePuy, Janssen and Merck Millipore.

Fergus Cawley – Senior E&I

Fergus is a highly experienced senior E&I engineer & Project Manager with a degree in Electrical and Electronic Engineering from UCC. Fergus specialises in the area of electrical power systems (LV/MV/HV, Power Generation, CHP and UPS systems) and sustainable energy. Fergus has worked across the Irish pharmaceutical industry as a senior electrical engineer and project manager. Recently Fergus has been the principal electrical engineer on several 2.4 MW data hall builds for Amazon Data Services in Dublin. Fergus was brought into BioPharma not only because of his strong CHP capabilities but also because of his ability to manage teams and disciplines. We believe he will be a valuable member of the team and you will all surely get to meet Fergus in the near future as he is brought into each of the ongoing and future BioPharma projects.