

# Integrated Commissioning & Qualification

## "engineering better solutions"

[www.icqconsultants.com](http://www.icqconsultants.com)

### International Events

Michael Bogan will be giving a presentation at the Commissioning, Qualification & Validation University held in Dublin, Ireland on November 28<sup>th</sup> through 30<sup>th</sup>. This conference will cover topics such as Commissioning & Qualification, Process Validation, Cleaning Validation, Computer System Validation and Data Integrity Compliance. Michael will be speaking along side Patrick Mullin of Shire on Integrated Commissioning and Validation of New Biotech



and Pharma Facilities. If you are interested in attending use code CQVU to save 10%! We wish him the best of luck!

### NE Events

ICQ is a **Gold Sponsor** for all NE PDA events. Please stop by our table at all upcoming PDA events and say hello!

ICQ recently participated in awarding \$18,000 in scholarships to six students with the PDA NE Chapter. Please join us in congratulating these students!



### Blogs

#### Magic Fields



Recently, I have been helping ICQ with internal support tasks. One such task involves the templates we will be using in the course of client project work, to standardize our communications.

#### Managing a Successful Plant Shutdown



A shutdown is a temporary closure of a facility or system(s), typically due to a malfunction, modification or for maintenance. Shutdown activities can be intense due to time constraints, budget, safety risks and workload.

### Services

#### Engineering Services

Our full-time professional staff can address a wide range of operational disciplines and issues, including capital projects, plant and equipment commissioning and decommissioning, and support for Commissioning, Qualification, Validation, Engineering, Quality Systems and Operation initiatives.

[Learn More »](#)

#### Validation Services

Whether you need a little help with protocols and documentation, or a full-scale program that takes you from initial planning through execution and, ultimately, regulatory approval, we have the know-how and the people to get the job done effectively and efficiently.

[Learn More »](#)

#### Technical Staff Augmentation

Running short-handed? Need to temporarily augment Engineering, Quality or Validation staff to handle project backlogs, Commissioning, Qualification, Validation, change control, mitigation plans or revalidation activities? We can help.

[Learn More »](#)

#### Quality Systems

With a solid grounding in state-of-the-art industry acceptance strategies, we can help you implement risk-based approaches that build quality into your process, ensuring compliance while maximizing operational efficiency.

[Learn More »](#)

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## On-Going Projects

ICQ has multiple staff stationed in Madison, WI in support of two major projects. This is a client program for a new process in which the client is the CMO (Contract Manufacturing Organization). The first project is to transform existing QC laboratory space into GMP manufacturing space. ICQ's scope includes: commissioning of the new lab space, qualification of numerous pieces of QC lab equipment, environmental qualification of the new mfg. space, and qualification of all new process equipment to support the new manufacturing process. The project is nearing completion with only a few last summary reports to wrap up. Major ICQ Team qualification responsibilities include: EQ of ISO7 and ISO6 rooms, refrigerator/freezer qualifications, several different QC instrument qualifications, process equipment qualifications (tube fusers, final fill finish dosing pumps, pneumatic capper), smoke studies for LFHs and BSCs, utility qualifications (process gasses, HVAC, process tempered and chilled water, purified water), author/review validation summary reports (VSRs), as well as wrapping up vendor qualification packages. The second project involves the addition of new manufacturing suites and GMP warehouse. With construction nearly complete and ICQ has started some facility commissioning activities as well as qualification of portable equipment. The new manufacturing space is comprised of several suites to accommodate the new manufacturing process (buffer/media prep, cell culture, through initial and final purification). The process primarily utilizes disposable equipment, with the exception of a few large scale pieces not currently available as disposable. ICQ will be commissioning and/or qualifying the facility and utilities: room fit / finish, process gasses, WFI, PW, HVAC, HVAC hot/chilled water, process chilled water, BAS and PCS. Manufacturing equipment qualification includes: disposable bioreactor shells, bioreactor rockers, TFF & NFF skids, Chromatography skids, LFHs, BSCs, buffer dilution skid, tube fusers / sealers and refrigerators / freezers.

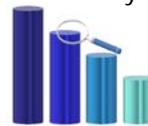
## 2017 ISPE Product Show

ICQ would like to thank everyone who stopped by our booth and said hello to our staff at this years ISPE Product Show. As always, the show was extremely well organized and a



## Metrics and Scheduling Services

Do you know the on-time status and progress of your program activities? With ICQ's scheduling and metrics services, we can give your company insight to the progress of your buildout, requalification, or documentation project. Scheduling and metrics can be prepared to your specification for any project that we assist you with.



# METRICS

## ICQ is Growing



ICQ is hiring, we are looking to employ motivated, talented individuals who share our passion for the industry! If you are looking for new challenges email: [resumes@icqconsultants.com](mailto:resumes@icqconsultants.com) You can also check out our latest hiring post to learn a little more about what we are looking for [here](#).

## Social Media

Click the Icons to follow ICQ's different social media sites and see our latest posts!



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