Reinventing tomorrow is our promise and an invitation to challenge what’s accepted and raise the bar in everything we do.

We design, build, commission, qualify and validate facilities right the first-time bringing client’s products to market faster; allowing patients access to the medicines they need.

As the largest engineering solution provider in the Life Sciences industry, clients benefit from our:

- Diverse workforce of 250+ engineering professionals dedicated to CQV. We have nearly 40 years of CQV and regulatory compliance experience.
- Global reach and local presence, enabling worldwide collaboration while reducing project delivery costs.
- Efficient integration with design, procurement, automation and construction to ensure quality assurance and speed up project delivery. We provide integrated solutions that minimize cost and schedule impacts, delivering facilities “Right the First Time”.
- Global CQV Quality System based on industry guidance and best practices, resulting in compliant and cost-effective solutions.
- Experience implementing science and risk-based strategies based on product and process knowledge and identified risk factors, allowing us to focus on critical aspects.
- Technical depth and expertise in all engineering disciplines, enabling Jacobs to support peak project demands or provide technical support.
- Subject Matter Experts in Cell and Gene Therapy, Biotechnology, Single-Use, Fill/Finish, and API. We deliver knowledge and expertise based on technical innovations.
- Safety Culture, BeyondZero®, which empowers our employees to create and sustain a positive, safe and healthy work environment.
Early involvement of CQV is imperative to design facilities that are right the first time, avoiding costly rework during Construction. During this phase we collaborate with design engineers to develop user requirements and perform risk assessments that serve as the basis for design and CQV strategies. In addition, we review equipment specifications, ensuring that FAT, documentation and data requirements are adequately addressed. We also support system boundary determination and system list development which are inputs to scheduling and estimating. Ultimately, we conduct design reviews ensuring that the designs meet user requirements and address critical aspects.

Our commissioning personnel work closely with Construction to build facilities that result in minimal issues during commissioning. We support factory acceptance testing and perform receipt verification activities to confirm that assets are correct prior to installation and are delivered with required documentation. We ensure alignment with system turnover requirements and expectations. We review construction and vendor documentation as it becomes available, not at mechanical completion. We conduct multiple system walkdowns with Construction. We provide construction quality assurance oversight to avoid downstream issues. We ensure safety is not compromised when assets are turned over to the commissioning team at mechanical completion.

During the commissioning phase, we begin performing verification activities to ensure that systems are installed properly, function safely per specifications and perform as intended. We perform these activities in accordance with good documentation practices and good engineering practices to ensure that the commissioning documentation can be utilized to meet qualification requirements, as part of a one-time testing approach. We implement a science and risk-based approach to ensure we are focusing on the critical aspects during Qualification, which typically consists of IQ, OQ and PQ. On many projects we have fully adopted the ASTM E2500 approach and utilize verification terminology in lieu of commissioning and qualification terminology.

We often provide validation support to help speed up our client’s time to market. We have computer system validation professionals that work with our C&Q teams to develop integrated testing strategies to deliver automated systems as efficiently as possible. We also provide cleaning validation support to confirm the effectiveness of cleaning processes, sterilization validation support to ensure sterility is maintained, and/or process validation support to ensure that quality products are consistently delivered. In addition, we develop SOPs and training materials, and provide maintenance services to support life cycle operations.

Why Jacobs?

We employ self-motivated, high-caliber CQV resources. We are an established Life Sciences market leader that has experience with emerging technologies such as gene therapy, cell therapy, nanotechnology and single use manufacturing. We leverage our large network of available SMEs to deliver value to our clients. We get client’s products to market faster with right-sized, scalable project delivery strategies. We partner with clients to focus on people, performance, safety and integrity, the principles of our Company. We minimize costs by using local resources in strategic locations around the world. We can accommodate any science and risk-based life cycle approach whether it is ASTM E2500, BG5 or GAMP 5. We use standard processes and data management tools to provide compliant and predictable turnkey solutions that streamline project delivery.

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