R-46917 Design Lead Engineer - Capital Projects

Organization Overview:
At Lilly, we serve an extraordinary purpose. We make a difference for people around the globe by discovering, developing and delivering medicines that help them live longer, healthier, more active lives. Not only do we deliver breakthrough medications, but you also can count on us to develop creative solutions to support communities through philanthropy and volunteerism.

Position Brand Description:
The design lead in IAPI (Indianapolis Active Pharmaceutical Ingredient) is responsible for providing owner/user representation, operational readiness leadership, and/or technical design oversight on large scale (>$5M) capital projects in partnership with Corporate Engineering.

Responsibilities:
• Delivering changes to current manufacturing processes to improve the quality, cost, or throughput capabilities of IAPI, and/or
• Leading commercialization efforts to integrate new large molecule insulin products or product variants to IAPI production, and/or
• Delivering site infrastructure projects that enable the IAPI site to achieve business plan targets.

Key Objectives/Deliverables:
• Provide Design Lead oversight as needed, including:
  o Establish user requirements and qualification plans to ensure that the equipment/system is appropriate for the intended purpose.
  o Establish conceptual, basic, and detailed designs for capital projects. Perform reviews of contracted designs for technical accuracy.
  o Feed process knowledge into the process design, utilizing tools such as modelling, historian data, technical reports, and industry literature.
• Provide Owner/User Representation as needed to ensure IAPI Operations or other Owner/Users are appropriately represented in all design, construction and verification activities. May include approvals on behalf of Operations or other Owner/User groups for project documentation, etc.
• Provide Operational Readiness as needed to ensure all site-driven operational readiness deliverables have been identified and performed to meet IAPI business schedule needs. Responsible for ensuring site performs all required activities post-construction to ensure asset is available for use per IAPI production timelines. This may include ensuring SOP/training readiness, organizational readiness, regulatory readiness, SAP preparedness, verification and validation planning and support, etc.
• Provide Project Leadership including:
  o Collaborate with internal and external customers to manage integration of assigned projects with other site and network projects
  o Provide regular communication to all levels of the organization via formal functional lead / steering teams and other ad hoc mechanisms.
  o Develop and manage overall project timelines as well as progress metrics
  o Lead cross-functional groups that enables the projects to move from inception to implementation.
Basic Requirements:
- Bachelor’s degree in engineering
- 2+ years of industry experience

Additional Skills/Preferences:
- Previous pharmaceutical manufacturing support experience, and solid understanding of the cGMPs.
- Previous process engineering experience, and/or experience in major capital delivery or project management.
- Previous expertise in bulk chemical processing (expertise with tanks, pumps, piping systems, purification, fermentation, distillation, high purity water systems, etc).
- Well organized, strong communicator.
- Ability to lead cross-functional teams.
- PE license and/or PMP certification.

Additional Information:
- Normal working hours are day shift, Monday-Friday. Occasional off-hour coverage may be necessary due to planned implementations or emergency support.
- Periodic updates to Senior Manufacturing Leadership may be required
- Travel is expected to be less than 10%
- Tasks require entering manufacturing and laboratory areas which require wearing appropriate PPE. Makeup cannot be worn in manufacturing areas.