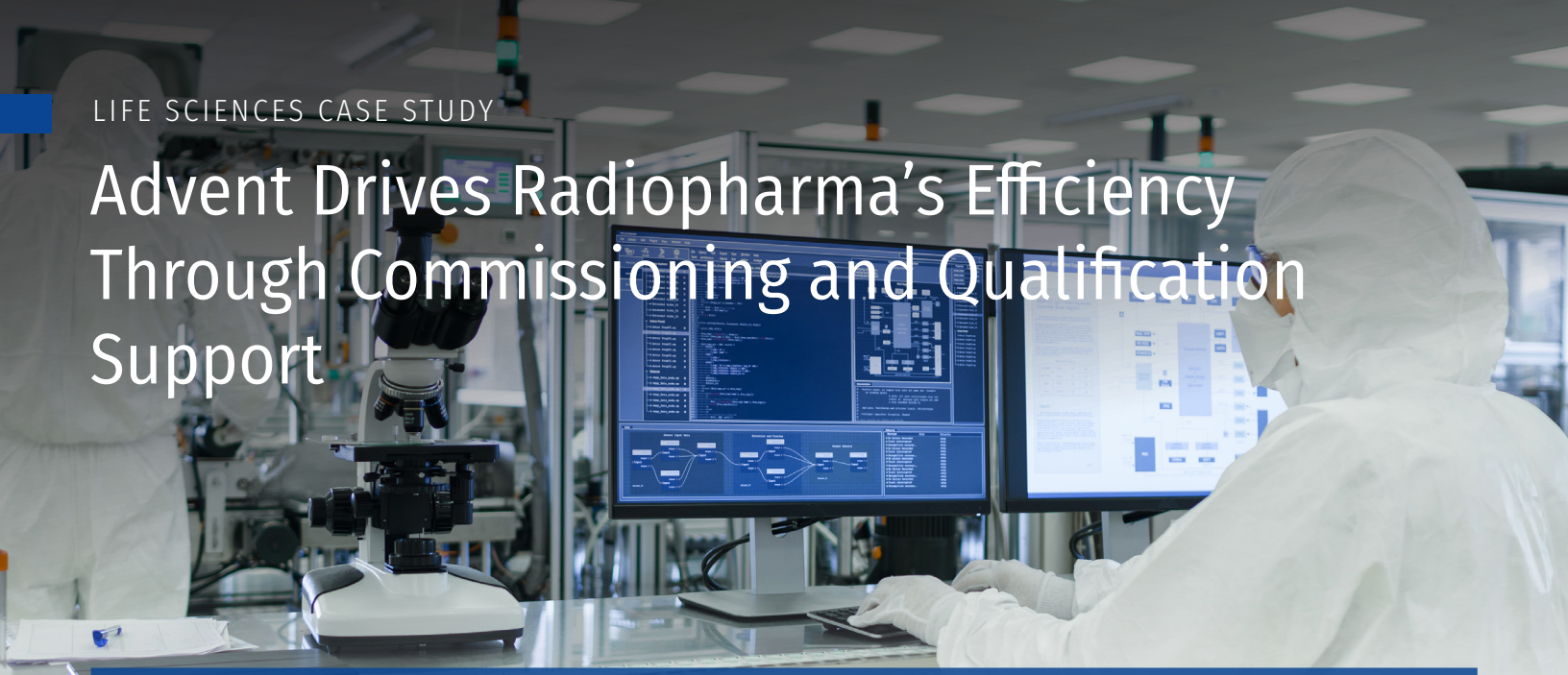

LIFE SCIENCES CASE STUDY

Advent Drives Radiopharma's Efficiency Through Commissioning and Qualification Support

CHALLENGE

A radiopharmaceutical manufacturing facility planned to expand from its existing site at a shared facility to a greenfield site with dedicated increased capacity. The project is on an aggressive timeline and phased to facilitate GMP production as soon as possible.

SOLUTION

Advent has been tasked with responsibilities for the Commissioning and Qualification of the entire building. The team has been engaged not only to deliver the testing and compliance documentation, but as a partner in their quality program to ensure the entire facility is compliant.

RESULT

The project is ongoing but has already driven many efficiencies for the quality program. Advent has begun streamlining documentation practices and is following a risk-based approach for C&Q efforts.

A radiopharmaceutical manufacturing facility planned to expand from its existing site at a shared facility. The new facility is a greenfield project dedicated for 10x increased capacity, spanning over 72,000 sq ft. The project is on an aggressive timeline and phased to facilitate GMP production as soon as possible.

Advent Engineering, a Trinity Consultants team, has been tasked with responsibilities for the Commissioning and Qualification of the entire building. The Trinity team has been engaged not only to deliver the testing and compliance documentation, but as a partner in their quality program to ensure the entire facility is compliant.

Trinity has leveraged decades of experience to bring value to this project. Trinity's expertise in construction, startup, and compliance has ensured that project delivery is on time and meets high standards. The team has worked to foresee roadblocks and produce a realistic schedule, utilizing several key touchpoints to monitor the health of the project and assess adherence to the project schedule and deliverables.

The project is ongoing but has already driven many efficiencies for the quality program. Advent has begun streamlining documentation practices and is following a risk-based approach to the site. This approach will employ a science-backed strategy for the site C&Q effort.

The risk-based approach combined with a family approach to the commissioning and qualification will enable the team to reap efficiencies to support the prompt release of the phases. The validation also has been planned to include efforts between the phases to account for any impact on the previously released areas.