

A Week in the Life: Senior Quality Assurance Associate



In access programs, quality is not a final checkpoint. It is built into every step. When patients are waiting, Sponsors need more than a vendor that can move product quickly. They need a partner with a strong Quality Assurance (QA) team that can help keep urgent activity controlled, compliant, and traceable.



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Monday: Priorities, Customer Qualification, and Patient-Focused Timelines

Mondays usually begin with a review of what has come in over the weekend and what needs to be prioritized for the week ahead. In QA, no two weeks look exactly the same. Some days are focused on client setup and documentation, while others are shaped by urgent operational questions, shipment timelines, or requests from Project Management and Supply Chain. One of the first things I look at is whether anything could affect a patient timeline or a shipment decision.

A large part of my role sits within GMDP Quality Assurance. GMDP refers to Good Manufacturing and Distribution Practice, the quality standards that help ensure medicines are manufactured, handled, stored, and distributed appropriately. In practical terms, that means working closely with the operational side of the business to support safe, compliant program delivery.

For access programs, that often starts with making sure the sites, hospitals, clinics, pharmacies, and other customers receiving product are appropriately qualified before anything is shipped.



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This work is detailed, but it is also very practical. Before product can move through the supply chain, QA needs to confirm that the receiving site is legitimate, qualified, and appropriate for the program. That can include reviewing documentation, checking customer details, verifying healthcare professionals, and making sure the site is correctly set up in our systems.

It may sound like a back-office task, but in an access program, it is directly connected to patient care. If a site is not qualified in time, a shipment may not be able to move. If a shipment cannot move, a patient may not receive treatment when expected. This is where a strong QA function makes a real difference for Sponsors: it helps protect patient timelines by making sure the fundamentals are right before operational pressure builds. One of the most rewarding parts of this job, for me, is knowing that the details we manage behind the scenes help ensure a patient receives the right treatment, on time, every time.

Tuesday: Working Across Project Management, Supply Chain, and Logistics

Tuesdays are often shaped by follow-ups from Monday. Once Project Managers have gathered the information needed from sites or Sponsors, QA reviews what has been provided and works through the next steps.

The role is highly cross-functional. I work closely with Project Management, Supply Chain, Logistics, Warehouse teams, and other QA colleagues to make sure each part of the process is aligned. A Project Manager may need a new site qualified for an urgent shipment. Supply Chain may need QA input on whether a certain warehouse pathway is suitable for a program. Logistics may need support if there is a question around documentation, delivery, or temperature conditions.

A key part of QA is making sure that speed does not come at the expense of control. Access programs often involve urgent timelines, but the process still needs to be documented, traceable, and compliant. Our job is to help teams move quickly, while making sure the right checks are in place before decisions are made.

This is one of the reasons communication is so important. We are embedded in the operations process, helping teams understand what is required, what risks need to be considered, and what documentation needs to be in place. In a vendor environment, this matters because access programs rely on multiple teams making decisions quickly. A strong QA team creates consistency across those handoffs, so decisions are based on clear information rather than assumptions.

Wednesday: Quality Agreements and Client Setup

Midweek is often a good time to focus on client setup and Quality Technical Agreements, commonly known as QTAs. When a new client comes on board, QA helps define quality responsibilities from the start. The QTA sets out how quality-related activities will be managed between WEP Clinical and the Sponsor. It helps clarify responsibilities around product handling, issue escalation, decision-making, documentation, release processes, and other program-specific requirements.

This is especially important in access programs, where products may move across countries, through different warehouse locations, and into a range of healthcare settings. Each program can look different depending on the countries involved, product requirements, storage conditions, warehouse partners, and the Sponsor's own internal processes.

Because of that, the QTA is not just a document to file away. It is a working reference point that teams may need to come back to throughout the life of a program. For me, this is one of the clearest examples of why QA matters. A well-structured quality agreement helps prevent confusion later and facilitates downstream speed. If an issue comes up, teams need to know who is responsible, who should be informed, and who has authority to make certain decisions. QA helps establish that clarity before the program is fully underway, and keeps track of it throughout the entire program lifecycle.

For Sponsors, that clarity can be the difference between a delay, an escalation, and a controlled decision.

A vendor with a mature QA team does not only respond when something goes wrong. It helps define the quality framework early, so the program has a clearer path when timelines are tight or requirements change.

Thursday: Supply Chain Oversight and Quality Control

Thursdays often involve working closely with our Supply Chain, Logistics, and Warehouse teams to make sure program activities continue to move in a controlled and compliant way.

In access programs, product handling and distribution need to be carefully managed. QA helps ensure that the right processes are followed, the right documentation is in place, and the right checks are completed before product moves through the supply chain. This includes supporting temperature-controlled storage requirements, warehouse documentation, customer setup, and internal quality processes linked to program delivery.

A big part of the role is making sure everything is traceable. For access programs, every step matters: where product is stored, how it is handled, which site it is going to, and whether the appropriate approvals and checks are in place. QA helps provide that oversight so operational teams can move efficiently while still working within a strong quality framework.

This oversight is also important because access programs are rarely static. Sites may be added, countries may change, timelines may accelerate, and product requirements may vary. Having QA embedded in the process helps ensure those changes are managed with control, rather than treated as last-minute administrative tasks. That is critical when Sponsors need a vendor that can stay flexible without compromising compliance.

Friday: Audit Readiness, Documentation, and Continuous Improvement

Fridays are often used to bring open items together and make sure nothing is left unclear heading into the following week. This may include following up on outstanding customer qualifications, reviewing documentation, checking the status of quality agreements, or making sure any ongoing deviations or investigations are progressing.

Audit readiness is also a key part of the role. Client audits, regulatory inspections, and internal reviews all require strong documentation and clear evidence that processes are being followed. QA helps prepare the relevant documents, supports the audit process, and makes sure that what is presented is accurate, complete, and compliant. If we have any audits coming up, I finish out the week by making sure we are on track and all internal stakeholders are up to speed on requirements and expectations.

The end of the week is also a chance to look at the bigger picture. Are teams escalating questions early enough? Are there process improvements that could make the next program smoother? Good QA is not only about reacting when something goes wrong. It is about helping the organization learn, improve, and prevent the same risks from happening again.

That mindset is important for Sponsors choosing a vendor partner. Strong QA does not slow a program down. When done well, it creates the confidence and structure teams need to move quickly, because the right checks, records, escalation routes, and responsibilities are already in place.


Why Quality Assurance Matters

Overall, the week for a Senior Quality Assurance Associate can move quickly. Priorities shift, urgent questions come in, and program needs can change from one day to the next. But the purpose of the role stays consistent: help ensure access programs are compliant, controlled, and ready to move when patients are waiting.

At WEP Clinical, QA plays an active role in program delivery. By working closely with Project Management, Supply Chain, Logistics, Warehouse teams, and Sponsors, QA helps build the structure and oversight needed to deliver access programs safely, efficiently, and with patient care at the center.

For Sponsors, this is why the strength of a vendor's QA team matters so much. Access programs often operate in complex, urgent, and highly regulated environments. A strong QA function helps reduce uncertainty, protect program integrity, support audit readiness, and keep patient needs connected to every operational decision. It is not a final checkpoint at the end of the process. It is one of the reasons the process can move forward with confidence.



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