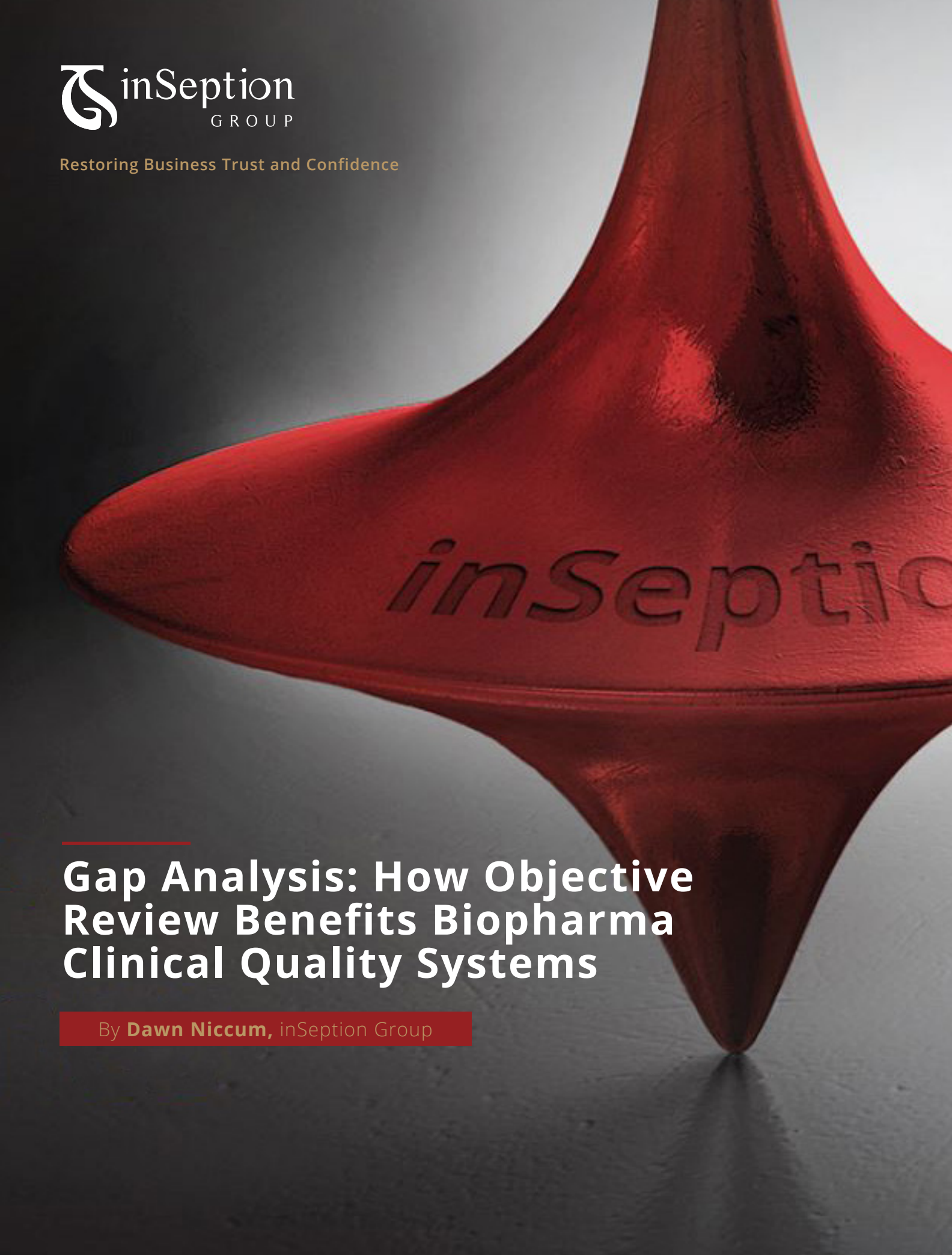
inSeption GROUP

Restoring Business Trust and Confidence



Gap Analysis: How Objective Review Benefits Biopharma Clinical Quality Systems

By **Dawn Niccum,** inSeption Group

A comprehensive gap analysis examines documented procedures, SOPs, and QMS processes, but also includes discussions with key personnel and scrutinizes outputs derived from those SOPs and processes.

Gap Analysis: How Objective Review Benefits Biopharma Clinical Quality Systems

By **Dawn Niccum,** inSeption Group

Many types of gap analysis exist within the clinical trial space, but gap analysis specific to a life science organization's quality management system (QMS) is among the most critical. It evaluates whether the organization has adequate processes, personnel, documentation, and systems in place to properly conduct its clinical trial. A gap analysis' key deliverable is a "report card" provided to the client — an independent analysis that can bolster the organization's confidence in its position moving forward, as well as help to identify, prioritize, and remediate potentially problematic areas.

Among the QMS shortcomings a gap analysis tends to expose, inadequate risk management often is the most prominent. For example, a company may strive to implement a careful, risk-based approach, but fail in the exercise of properly documenting that risk-based approach (and, per the industry adage, "if it's not documented, it didn't happen"). Document management often emerges as the second-most prominent issue. Again, the company might have good procedures in place, but it has utilized a non-validated system to store documentation or a system that does not provide continuous, user-friendly access to controlled documents.

Finally, gap analysis often discovers vendor management problems, including lack of adequate vendor oversight or qualification. Oversight is not indicative of a lack of faith in the vendor, but rather a regulatory requirement. It helps ensure your organization has done everything possible to conform to applicable regulations and to protect all patients participating in the trial (in terms of both human subject protection and data integrity). The best way to implement quality in a process is to plan for its inclusion — and double-check it — at every step.

WHEN TO PERFORM GAP ANALYSIS

Gap analysis often is requested when a client already is in a later phase of clinical development, such as Phase 3, but initial entry into the clinic is the ideal time to conduct a gap analysis. The later a gap analysis takes place, the more remediation becomes necessary to address issues that have been identified. And, the farther along a product is in development, the more difficult it becomes to make changes. Not only must procedures potentially be changed, so must personnel training and day-to-day behaviors that have been ingrained.

In addition to being more straightforward, gap analysis conducted early in development typically is less expensive, both in terms of executing the analysis and in terms of problem remediation, because it is less likely to discover issues requiring remediation. Gaps identified early tend to be more future-looking and allow for new and updated procedures to be implemented before they need to be utilized. So cost, risk, and timeline impact increase with later-stage gap analysis, as does the likely extent of remediation efforts. In short, one cannot retroactively build quality into a process that already has been implemented.

Still, gap analysis' benefits are highly situational. For example, if a company is entering a Phase 3 that will span four or five years, changes based on the gap analysis probably can be quickly implemented and standardized moving forward. A product and process less than one year from NDA or MAA submission, meanwhile, draws different value from gap assessment. The exercise still provides the client organization with information and context regarding the state of its project (i.e., so the client receives no surprises at inspection), but the remediation becomes much more challenging.

Such a late-in-the-game assessment may not help the client with the current study, but it may save a submission if the company can show continuous improvement activities (which can support a company through an inspection). Additionally, depending on the organization's pipeline, the analysis' findings may be applicable to its future trials — products still in proof-of-concept, preclinical, or early clinical development.

ACTIONABLE FINDINGS REQUIRE COLLABORATION

A fruitful gap analysis looks at more than just documented procedures, SOPs, and QMS processes. It includes interviews with key personnel, looking at outputs derived from those established SOPs and processes. For example, an SOP on deviations/quality events and CAPA: what quality events has the client experienced, and how were those events handled? Or, if a study has experienced significant compliance issues, what steps have been taken to ensure out-of-compliance investigators get back on track and remain there? Who has been involved in that decision-making and remediation?

In short, speaking to these individuals is critical to a quality consultant's ability to understand the client's awareness of its own processes, as well as their perception of what gaps may exist. In addition to the end-of-analysis report detailing QMS elements that are adequate or need improvement, an in-depth gap analysis often can subsidize that "report card" with suggestions for how the client might proceed. Remediation steps might be as simple as adding necessary SOPs: policies, training, or not-yet-completed audits the client could consider.

The gap analysis process typically takes place organically, in that quality consultants do not know which direction the exercise will take until they are digging into the client's quality system and engaging critical personnel in those probing conversations. This thorough approach ensures the client derives maximum value for their cash and time investment: a report with clear deliverables to inform next steps, whether that entails additional personnel, enhanced training, or in-depth review of a particular (sub-)process that has emerged as a pain point.

A comprehensive gap analysis includes the client — who might be a clinical quality person, a CEO, or functional area senior management, depending on the size of the company — in findings as it is ongoing, rather than simply producing a one-off report at the end. What should the client focus on first? Which compliance issues must be solved immediately and what needs to be in place when we go to market? Biopharma organizations should seek a partner agile enough to tweak the analysis based on their feedback regarding what might be helpful. A one-size-fits-all approach is ill-suited to an exercise designed to provide client- and situation-specific guidance, particularly since the gap analysis is a start, not the end, to QMS and process optimization.

The gap analysis process typically takes place organically, in that quality consultants do not know which direction the exercise will take until they are digging into the client's quality system and engaging critical personnel in those probing conversations.

FINAL THOUGHTS

A biopharma can have great faith in its personnel and partners, but the onus ultimately falls on that sponsor to "trust, but verify" — to show regulatory agencies and stakeholders in its clinical trial(s) it has confirmed what its QMS supports and ensured that established procedures are being followed. Gap analysis delivers this "insurance policy" in terms of helping to identify and mitigate risk, giving sponsors confidence in their ability to progress to the next level of their trial and beyond.

Gap analysis typically begins with a vendor/client meeting where, through discussion and sharing of SOPs, quality consultants begin to form a mental image of the client organization: which people and systems are adequately in place, and what must be implemented to take the client where it wants to go? Interviewing people throughout the organization about their needs and pain points

further informs the analysis. When the client is struggling to glean a quality outcome from a vendor, some aspect of the study, a site, or its people, what root causes are to blame? All those inputs are considered to formulate a plan specific to the client and the project.

Capable gap analysis partners then can provide guidance to the client or, in cases where the client wishes to implement its own updated approach, analysts can review their outputs/remediation initiatives. While some clients lack the bandwidth to assign that task to internal personnel, for those who can, the most successful output a gap analysis can produce is helping a client to a point where they no longer feel they need additional guidance or assistance.

To learn more about QMS gap analysis and how ISG can help, visit us at www.inseptiongroup.com/quality-assurance.

To learn more, call:
Joseph Arcangelo Sr.
Co-Founder and Managing Partner of
inSeption Group
Jarcangelo@inseptiongroup.com
267-498-5092

ABOUT InSEPTION GROUP

Unified in our passion to bring therapies and an improved quality of life to patients around the world, we will only provide solutions that increase speed and efficiency in making available life-changing treatments to the patients we serve.

We build the foundation for success by assembling an elite team for every client, every time. Every team member has a mutual passion and an insatiable desire to share in offering hope and making a difference for the patients we serve during their fight for a better, longer life.

We believe that only teams of functional experts, who share personal attributes of excellence and grit, can deliver transparency, precision, and certainty to an industry that is rife with complexity and disappointment.

inSeption GROUP