THE CHALLENGE

A mid-size Biotech client had roughly doubled the number of compounds in development. Additionally, it was expecting to increase that number by roughly 50% within the next two years - and an important FDA filing. For the client to handle the increased workload while ensuring rock solid compliance, it asked for Pharmica's help in both determining where the gaps were and the remediation of these gaps.

HOW PHARMICA HELPED

Pharmica's compliance experts sat down with the key stakeholders to hear about how they were operating and reviewed all supporting documentation, such as SOPs, work instructions, guidelines, and tools & templates. Pharmica wrote a clear and concise Gap Analysis Report which called out the deficiencies by area, referring directly to FDA guidelines so the client could see the root of the problem. After facilitating prioritization of the list of compliance gaps, Pharmica set to work in remediating each issue, through writing SOPs, work instructions, and guidelines, and developing tools and templates where needed. Pharmica also recommended additional technology solutions to not only make sure the client would remain compliant, but that it would do so in the most efficient and painless way possible.

LASTING RESULTS & RELATIONSHIPS

In the end, the client's collective stress level dropped tremendously knowing that all the compliance gaps were closed. Potential fines and delays in drug approval were avoided, and now it was able to move ahead with a more compliant mindset towards future clinical development.

Building quality systems and improving compliance within your organization can be a thankless task – but it's critical for long term success. Whether you are struggling with out of control processes, or you need a quality systems overhaul, Pharmica can address your quality needs. We'll help you understand the current regulations, put in place the systems, procedures, and learning to ensure consistent compliance. When audits become clear sailing, you'll be thankful you did.