

RETURNING TO GREENFIELD

by Steve Snyder

Steve Snyder is an independent consultant with more than 40 years of experience in toxicology operations. Covance has retained Steve to provide guidance and support for toxicology operations at their Greenfield, Indiana research site.

In September 2017, I returned to Greenfield, Indiana to visit one of the nonclinical facilities of Covance. As I neared the facility, memories from my past career returned.

I joined Eli Lilly in 1989 as a toxicologist at the Greenfield campus, eventually moving into a management role focused on improving operational productivity and tightening regulatory compliance practices. Ten years later, Lilly's general toxicology business was transformed into a highly effective operation that utilized metrics to manage all key processes.

Around 2004, Lilly made a business decision and converted all toxicology studies to discovery and lead optimization activities. The lack of regulatory rigor in a toxicology operation reduces quality metrics.

Covance purchased the Greenfield site in 2008 and GLP toxicology capabilities were re-established beginning with developmental and reproductive toxicology in 2012 and general toxicology in 2016. Fast forward to September 2017 when I returned for a visit and was pleasantly surprised. Good things have been happening at the Greenfield campus, including in the areas of:

- ▶ **Management** – Greenfield's toxicology operations are under new management. These individuals have more than 120 years of combined experience.
- ▶ **Commitment and Investment** – From the day that LabCorp announced it had acquired Covance, many have been contemplating what would happen to the nonclinical operations. Rest assured, LabCorp is continuing to invest in the nonclinical operations of Covance with:
 - A recently established, robust global immunology and immunotoxicology unit
 - Staff increases at multiple facilities
 - A new, state-of-the-art large animal necropsy room at Greenfield
 - System and software upgrades including ePlanning software, which maximizes staff effectiveness and study oversight
- ▶ **Harmonization** – All SOPs for GLP operations from the Covance facility in Madison have been implemented at Greenfield, bringing procedural harmonization across facilities.
- ▶ **Training** – In my opinion, Covance has one of the most robust training programs in the CRO industry. Technical trainers circulate among the study rooms to provide real-time procedural quality control. If a particularly complex procedure is being performed during a study, the trainers will be present to provide oversight and support.
- ▶ **Replacement, Reduction, Refinement** – The progressive animal welfare practices at Greenfield rival other industry-leading initiatives. Key practices include: colony dogs getting periodic “play days” in a dedicated room and European-style caging for nonhuman primates being established.

As nonclinical outsourcing continues to improve, capacity is tightening across the industry. Greenfield is a viable GLP alternative, but the word is not yet spread throughout the client community.

As a consultant, what does this mean for you? When we outsource nonclinical work, risk mitigation is a significant concern. To ease some of that risk, I will be onsite at Greenfield regularly to oversee ongoing operations. With your permission, I am offering to provide an additional layer of operational oversight on your studies. I will work with the management team to facilitate a smooth and successful experience for your client's nonclinical program.

As an independent, nonclinical study monitor, I represent clients at CROs to make sure their studies are conducted in accordance with the study protocol and that all activities are compliant with regulatory guidelines. My work at Greenfield will not only allow me to share my monitoring experience, it will also give me visibility and input to the actual toxicology operations, thereby providing an extra measure of risk mitigation for you.

Covance is currently offering to pay some travel costs of consultants visiting the Greenfield campus to learn more about their GLP toxicology capabilities. If you would like to learn more about the GLP operations at their Greenfield site, please feel free to contact me directly at info@outsource-support.com.

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