



LAB FORWARD™

CLARKSTON
CONSULTING

THE CASE FOR CHANGE

Medicine is changing. Advances in platform technologies and personalized treatments are fundamentally changing the way drugs are discovered, manufactured, and delivered. However, in this rapidly evolving world, laboratories lag behind. It is not uncommon to find antiquated equipment, decades old systems, with practices and processes that are so established, so routine, that no one questions or even remembers why they are the way they are.

After working in pharmaceutical laboratories for the past 25 years, Clarkston's consultants have seen tremendous opportunity for operational improvement within the labs. Beyond this however, we believe that we are at an inflection point where new enabling technologies will reshape the way that labs support research, development, quality, and manufacturing. The question is not whether change is coming, but rather, are you positioned to take advantage?

To answer this question, Clarkston created LabForward.

WHAT IS LABFORWARD?

LabForward is Clarkston's industry leading laboratory optimization service. For forward thinking executives in Research, Development, Quality, and Operations, LabForward will deliver you:

- Real financial improvements within and across your laboratory network.
- A realistic and pragmatic roadmap to transform your labs by taking advantage of advances in systems, processes, and technologies.
- A cost / benefit and return on investment justification.

Simply put, LabForward will help you maximize what you have today and prepare you for tomorrow.

THE LABFORWARD APPROACH

LabForward is designed to work if you have one lab or an entire network of labs. This initiative would start with a rapid and systematic review of products, processes, organization, equipment, and systems. The review is done with a focus on identifying opportunities for improvement from the dimensions of efficiency, quality, and simplicity.

- Efficiency: Concerned with speed, consistency, and resource optimization.
- Quality: Concerned with error reduction, data integrity, and building in systemic improvement.
- Simplicity: Concerned with removing complexity that has grown over time due to traditional methods and ingrained ways of doing business.

From this review, our laboratory experts will be able to quickly provide you with recommendations based on their years of experience, industry best practices, and most importantly the application of new enabling methods and technologies including Cloud Based Solutions, Collaboration Platforms, Scientific Data Management Systems, Laboratory Wearables, and Hyper-Logistics.

Recommendations will include quick wins as well as more systemic improvements outlined along a roadmap with clear cost / benefit and return on investment justification.

As an outcome of a Clarkston LabForward Assessment, you can expect real operational improvements along with a clear case for change.

LABFORWARD ASSESSMENT and BENEFITS CASE

The LabForward Assessment and benefits case focuses on what you make (therapeutic footprint of today and tomorrow) and how you make it (maturity of efficiency, quality, and simplicity). The remainder of this paper details each of these areas, what is important to consider about each one, and the potential benefit profile to be attained.

Therapeutic Footprint Today and Tomorrow

A key element of the LabForward approach comes with a thorough understanding of drug types, delivery methods, and dosage forms. The opportunity to reduce cost and improve efficiencies from economies of scale and lab

innovation can be attained in looking across an entire drug portfolio. A full assessment would identify synergies across therapeutic categories which would then dictate improved options for business partners in and across functions including research, development, commercialization, and commercial manufacturing. These synergies will be increasingly more important for platform therapies and with personalized medicine. The top **therapy** areas in developed pharmaceutical markets projected through 2021 include the following:

- Oncology
- Diabetes
- Autoimmune
- Pain
- Cardiovascular
- Respiratory
- Antibiotics and Vaccines
- Mental health

Lab capabilities should be planned on a continuum to understand needs and impacts to infrastructure, clinical operations, manufacturing, and quality systems.

To diagnose your biggest opportunities a LabForward assessment will examine your capabilities, partners, and future needs in the following areas:

- Solid Dosage Forms and Solid Modified release Drug Delivery Systems (e.g., powders, capsules, tablets)
- Semisolid Dosage Forms and Transdermal Systems (e.g., ointments, creams, gels, transdermal)
- Suppositories, Inserts, and Sticks
- Liquid Dosage Forms (e.g., solutions)
- Sterile Dosage Forms and Delivery Systems (e.g., parenterals, biologics, special solutions and suspensions)
- Radiopharmaceuticals
- Biologics
- Advanced Delivery Systems and Devices

Specific to emerging areas, a LabForward assessment will evaluate needs for research, development, chemistry manufacturing and controls (CMC), clinical, diagnostics, and commercial manufacture. Emerging areas include:

- Antisense and RNAi Based therapeutics
- Protein therapeutics (including Cancer Immunotherapy)
- Genomic Editing (CRISPR-Cas9)
- Next Generation Sequencing: Early Cancer Detection – Liquid Biopsy Assays
- Microbiome
- Metabolomics
- Proteomics
- Genomics and Epigenetics
- Biologics Front-Screening
- Antibody-Drug Conjugates

Companies who take a comprehensive look at their lab strategy will find a variety of tangible benefits. Some of the common benefits from a LabForward assessment include:

AREA of FOCUS	BENEFIT CATEGORY
Rationalizing partners based on therapeutic and delivery capabilities can result in increased R&D productivity.	• Time to Market • R&D Pipeline Efficiency • R&D Return on Investment
Anticipating laboratory needs by mapping to future requirements can result in accelerated tech transfer, consolidation of purchasing power, and advance proof of concept to reduce rework and cost.	• Time to Market • Cost Reduction • Cost Avoidance
Rationalizing supply chain and supply chain partners can result in reductions in cost and improvements in core quality metrics including data integrity.	• QC/ QA Conversion Cost • Right First Time Quality • Reduction in Incidents and Investigations • Increased Data Consistency and Integrity

EFFICIENCY: MAXIMUM PRODUCT



Are you concerned with speed, consistency, and resource optimization? LabForward provides a pragmatic roadmap to transform your labs by taking advantage of advances in systems, processes, and technologies.

LabForward includes a maturity assessment and recommendations related to the **efficiency** of your laboratory operations (within and across networks). Significant business benefits can be attained through intelligent laboratory design for new labs and redesign for labs already in operation. Areas of focus include:

- Laboratory network design including intra-lab, intra-company, and with business partners.
- Sample chain of custody from creation through disposal.
- Laboratory processes, procedures, and work instructions.
- Consumable and supply management.
- Metrics and measures.

Beyond this, application of advanced capabilities such as artificial intelligence, productivity wearables, workflow management cockpits, cloud based integration for suppliers, and hyper-logistics can make transformative impacts on efficiency gains.

The benefits that companies can realize from a focused effort of improved efficiency in their laboratory are numerous. See the table below for several tangible results companies could expect:

AREA of FOCUS	BENEFIT CATEGORY
Rationalizing contract partners and consolidating like testing can result in reductions in cost and improvements in core quality metrics including data integrity.	• QC/QA Conversion Cost • Right First Time Quality • Reduction in Incidents and Investigations • Increased data consistency and integrity.
Optimizing sample chain of custody and laboratory processes, procedures, and work instructions can result in increased laboratory throughput and improvement to core quality metrics including data integrity.	• QC/ QA Conversion Cost • Batch Release Cycle Time • Increased data consistency and integrity
Consolidating sourcing for consumable and supply management can reduce costs and increase real time availability of supplies in the labs.	• Cost reduction • Reduction in Batch Release Cycle Time

QUALITY: DATA INTEGRITY & ERROR REDUCTION



Are you concerned with error reduction, data integrity, and building in systemic improvements across your labs? LabForward leverages years of experience and industry best practices to provide real improvements within and across your laboratory network.

LabForward includes a maturity assessment and recommendations related to the **quality** of your laboratory operations (within and across networks). Significant business benefits can be attained through intelligent quality system design, elimination of handoffs and manual activities, improved training, and the use of productivity wearables. Areas of focus include:

- Maturity and usability of all quality management processes and systems supporting laboratory operations.
- Automation profile, nomenclature, data model, and integration points allowing “leakage” of data integrity.
- Maturity of training processes, systems, and controls.
- Maturity of corrective action / preventative action (CAPA) capabilities to make systemic improvements that reduce repeat error profile.
- Metrics and measures.

Major improvements can be made with productivity wearables, virtual monitoring of laboratory operations, virtual reality training, and predictive analytics for investigation and CAPA management.

Some of the examples of benefits that can result from reviewing and implementing best practices related to improving data integrity and reducing laboratory errors includes:

AREA of FOCUS	BENEFIT CATEGORY
Simplifying quality processes and systems can result in better first-time quality and faster resolution of issues.	• Reduction in Incidents and Investigations • Increased data consistency and integrity
Reducing manual steps and hand-offs between systems that manage quality processes and data can result in reductions in errors, increased laboratory throughput, and improvement to core quality metrics including data integrity.	• QC/QA Conversion Cost • Batch Release Cycle Time • Reduction in laboratory and manufacturing errors • Increased data consistency and integrity
Transforming the way that training is developed, delivered, and managed (including VR Training Laboratories) can have material impacts on product quality.	• Analyst Replacement Costs • Reduction in laboratory and manufacturing errors

SIMPLICITY: ELIMINATE UNNECESSARY COMPLEXITY



The LabForward approach will help you deliver real financial improvements within and across your laboratory network with a cost/benefit and return on investment justification. Save money by cutting out the excess.

LabForward includes a maturity assessment and recommendations related to the **simplicity** of your laboratory operations (within and across networks). Complexity creeps into process and systems designed to fulfill specific functions and added / changed over time. Complexity “Creep” and Data Integrity “Leakage” are solved through a focus on simplifying operations. Areas of focus include:

- Processes, procedures, work instructions, layouts, and ergonomics
- Sample and material flow within and between laboratories, sites, and supply chain partners
- Data management requirements and capabilities (manual versus automated)
- Ready to execute capabilities for QC and QA personnel at all levels
- Maturity of training processes, systems, and controls
- Metrics and measures

Significant improvements can be made by looking at quality processes and systems as a whole and asking questions about why things are done the way they are. Often times processes have either not evolved as needs have changed or they have changed incrementally over time to introduce complexity. The use of virtual reality and modeling capabilities lets you envision intelligent and simplified design.

By reducing complexity within one lab or across a network of laboratories, you can deliver real financial improvements and save money cutting out the excess. The real challenge is knowing where to look for these opportunities without sacrificing the quality of your output. Here are some real results companies can expect from simplifying laboratory processes and operations:

AREA of FOCUS	BENEFIT CATEGORY
Simplification of processes, procedures, and work instructions can result in immediate “quick wins” for personnel and core quality metrics.	• QC/QA Conversion Cost • Batch Release Cycle Time • Increased ready-to-execute metrics • Reduction in non-value added time
Optimizing layout and introducing modern ergonomics (including wearables) can also result immediate “quick wins” for personnel and core quality metrics.	• QC/QA Conversion Cost • Batch Release Cycle Time • Reduction in laboratory and manufacturing errors • Reduction in Incidents and Investigations • Increased data consistency and integrity

AREA of FOCUS	BENEFIT CATEGORY
Introducing ready-to-execute concepts on the bench and in the review process both in QC and QA can reduce laboratory cycle time and increase throughput / revenue	• Batch Release Cycle Time • Plant Revenue Contribution • Reduction in laboratory and manufacturing errors • Reduction in incidents and investigations
Transforming the way that training is developed, delivered, and managed (including VR Training Laboratories) can have material impacts on product quality.	• Analyst Replacement Costs • Reduction in laboratory and manufacturing errors
Introducing artificial intelligence and predictive analytics can also simplify decision making about decision points such as when to open an investigation, when to do a retest, when to re-order consumables, and many other routine decisions that require human intervention.	• Reduction in Incidents and Investigations • QC/QA Conversion Cost.

ARTICULATING THE CASE FOR CHANGE

The LabForward Assessment takes a comprehensive look at your laboratory strategy and process and organizes recommendations into cost / benefit justified improvements. The output of the assessment then prioritizes the recommendations into a roadmap that includes an evaluation of when costs will be incurred and when benefits will be achieved. This information provides you and your organization the assurance of accuracy and predictability as you look to move your labs forward into the next year of pharmaceutical research, development, and manufacturing.

Consider the following case study examples:

GLOBAL HARMONIZATION OF LABORATORY OPERATIONS

One of the world's leading biopharmaceutical companies worked with Clarkston to modernize and transform their laboratory operations. This included creating common processes, methods, and equipment standards. It also included transforming supply networks by creating centers of excellence for common test requirements.

Across the global network of sites, the results were compelling, including reduction in error rates, decrease in batch release cycle times, reduction of the cost of laboratory operations, and most significantly the ability to quickly add new capabilities required to integrate new products in a fast, dynamic, and ever changing product and facility landscape.

EXCELLENCE IN RESEARCH and DEVELOPMENT

One of the world's leading Contract Development and Manufacturing Organizations worked with Clarkston to optimize the labs in their research, development, and Chemistry Manufacturing and Controls (CMC) business operations. The purpose was to both maximize current capabilities, as well as to position for future offerings in areas such as RNAi, Genomic Editing, Liquid Biopsy, Microbiome, Biologics Front-Screening, and Antibody-Drug Conjugates.

The results for this organization included a 20% increase in analyst capacity, a 25% decrease in cycle time, and a 45% rise in group profitability. However, the more powerful and compelling outcomes were found in the ability to position for new market offerings and to connect with cloud based solution providers allowing pharmaceutical researchers bring treatments and cures to market faster and more confidently than ever before.

A BRIGHTER FUTURE WITH LABFORWARD

In the past 5 years, more new treatments have been brought to market than in the previous 25 years combined. The ability to discover, commercialize, and deliver advances in medicine will only continue to accelerate. And given this accelerated rate of advancement, the laboratory operations of the last 25 years will not meet the needs of the next 25 years of innovation. LabForward is your link to creating the future of laboratory operations for your business today.

About the Author



JOE D'AMBROSIO,
PARTNER

Joe is a partner in the Clarkston Management Consulting practice. In this capacity, he works with client leadership on breakthrough strategies that deliver business results and shareholder value. Joe has spent 25 years working with global clients in the life sciences and consumer products industries. He has advised on all aspects of business strategy, innovation, mergers and acquisitions, and operations.



AT CLARKSTON, WE MAKE YOUR PURPOSE, OUR PURPOSE.

Since 1991, we've worked with the world's leading life sciences companies to accomplish their most critical business objectives. Our vision is to be the most effective and highly sought after integrator of business solutions for our core clients, promoting business growth and market diversification, while providing a rewarding and stimulating environment for our stewards.



SCHEDULE A FREE DIAGNOSTIC EVALUATION

CLARKSTON
CONSULTING

