Tunnell
STRONGER PERFORMANCE AHEAD®

Lean Product Development

Speed Time-to-Market and Reduce Costs

The need for faster pharmaceutical and biotechnology product development has never been more urgent. Over the next three years, $89 billion worth of drugs will lose patent exclusivity, shrinking revenue streams for brand companies and opening up opportunities for generics. Brand companies urgently need to replace those revenue streams, and generic companies need to be able to secure first-to-file advantages. The value of faster product development is enormous: every day saved in bringing a major new drug to market is worth nearly $250 thousand in cost savings and more than $1 million in revenue; a month is worth $7.6 million in cost savings and tens of millions in revenue.

An Integrated Solution for High Costs and Long Development Cycles

Delays in product development have disparate sources: process inefficiencies, poor quality, too many concurrent development projects that strain resources, inadequate project management tools, and multiple problems in clinical trials. Piecemeal approaches to these challenges merely get products to the next bottleneck faster – and make it worse. Tunnell Consulting provides an integrated solution for addressing all of these sources of delay simultaneously.

Lean Product Development *from Tunnell Consulting dramatically lowers costs and reduces cycle times. This powerful solution combines three proven methodologies that work together across all dimensions of product development:*

3 Methodologies

1 Integrated Solution

Lean

Eliminates waste, increases efficiency and speed.

QbD/Six Sigma

Builds quality into products and processes.

Human Capital Alignment

Builds leadership, aligns skills and capabilities and enables culture change to ensure sustainability.

Benefits

Lean Product Development *generates significant business and operational benefits, including:*

- Reduced time and cost to market
- Accurate prediction of development time and costs
- Increased capacity of process and product development processes
- Reduced time and cost for regulatory submissions
- Decreased time to approval of submissions
- Reduced non-compliance notifications
- Reduced time and cost to a capable commercial manufacturing process
- Knowledge transfer that enables the organization to sustain improvement in product development, apply powerful methodologies to other improvement projects, and execute all projects more efficiently

From maximizing the ROI of your development portfolio, to driving out inefficiencies and improving the reliability of development processes, to eliminating clinical trials delays and repeats, these methodologies work synergistically to optimize the entire end-to-end development process.

With nearly 50 years of experience helping life sciences organizations implement improvements, we help organizations break the cycle of disappointing piecemeal solutions. Our multi-disciplinary team of life science process experts, process engineers, and business consultants includes members who have experience working for the FDA in such roles as field investigator, compliance officer, drug specialist, and in the regulatory laboratory – experience that can be invaluable during all phases of product development. Their collaborative approach to implementation and knowledge transfer leaves the organization with core competencies in product development and process improvement, as well as the ability to execute all improvement projects efficiently and at lower cost.

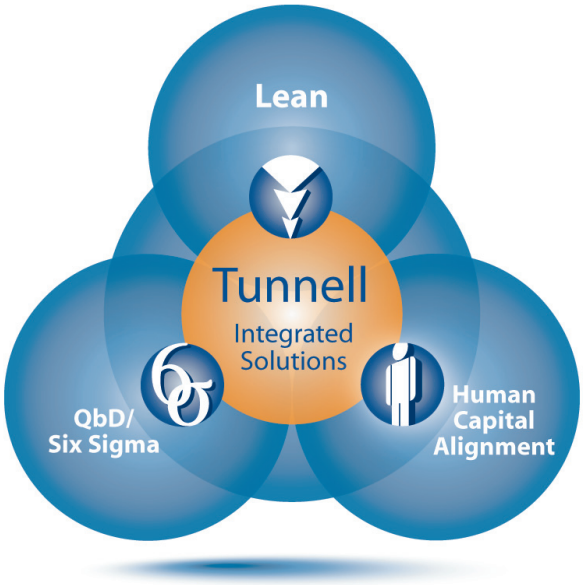
Getting Results

Tunnell's unique approach to product development *has produced faster time to market and bottom-line benefits for leading pharmaceutical, biopharmaceutical, and generics manufacturers in all phases of product development. Results include:*

- Delivering a process/product one month early with a 30-fold ROI to client in the first year
- Achieving a greater than 30% increase in laboratory throughput/productivity, with bottom-line savings to the company of $2.1 million annually
- Designing an efficient method in clinical trials for conducting the third-party studies (TPS) process, including contract negotiations, protocol development and drug supply
- Decreasing the overall time to build an electronic case report form by approximately one-third, from 12-15 weeks to 8-10 weeks and identifying an additional cost avoidance of approximately $2.5 million
- Making 13 process improvements and 13 system/technology improvements in clinical trials management, resulting in an estimated $2.2 million in cost avoidance
- Resolving dissolution batch issues so that product was launched on time

Addressing Key Development Challenges

Each of our proven methodologies *– woven into a powerful, integrated solution – addresses the many challenges of drug development throughout the process.*



Lean

- Increases efficiency by eliminating unnecessary hand-offs and activities and simplifying processes
- Ensures material availability for clinical trials and eliminates unneeded inventory via Lean Flow and Pull
- Error-proofs products and processes to improve Right First Time (RFT)
- Utilizes advanced scheduling tools such as Critical Chain Project Management (CCPM) to ensure on-time and on-budget completion of development projects

QbD/Six Sigma

- Evaluates multiple factors faster, heading off repeat trials and identifying non-viable projects earlier by building quality into trial design
- Provides a thorough understanding of processes and risks involved in manufacturing the API and drug product, and of how best to mitigate those risks
- Enables rapid technology transfer via Technology Transfer by Design® (TTbD)
- Utilizes tools such as simulation to understand variation and its impact on processes and products

Human Capital Alignment

- Designs the organizational structure to ensure the right staffing and skill sets to accomplish strategic objectives
- Enables and sustains culture change by aligning behaviors with the vision of the company, its values and beliefs, and its desired operating environment
- Aligns the composition/capabilities of the workforce with organizational performance expectations
- Develops the required leadership mindsets
- Builds performance metrics and processes to ensure sustainability

Our Approach

We begin with an opportunity assessment of the development process, which typically involves such functions as process development, technical services, analytical, pre-clinical, clinical, QA, regulatory, finance, and others. Through data mining and analysis we quantify and prioritize strategic and operational opportunities. Then, with a clear and efficient implementation roadmap, we work collaboratively with the client to harness the power of their knowledge of their business and our strategic, operational and technical expertise in pharmaceutical and biotechnology. With a long track record of accelerating product development and reducing costs, Tunnell Consulting is the partner of choice for companies that must get to market faster and more reliably.

For more information about how **Lean Product Development** can dramatically reduce the time and costs of product development and get you to product launch faster, please call **610.337.0820.**

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Founded in 1962 and serving many of the world's leading life sciences firms, Tunnell Consulting integrates strategic, technical, process, and organizational skills to design and implement sustainable solutions that exactly meet client needs. With deep industry knowledge, extensive scientific credentials, and superior measurable results, we consistently boost the operating performance of each unique client we serve.

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