2012 Case Study: Training Drives a New Business Model

NPS PHARMACEUTICALS

Life & Health

NPS Pharmaceuticals is an emerging development powerhouse that effectively brings biopharmaceuticals to patients with unmet medical needs. The company's lead clinical programs are innovative therapies for patients with rare gastrointestinal and endocrine disorders. NPS is advancing two late-stage programs. A New Drug Application is undergoing FDA review for GATTEX® (teduglutide) as a treatment for adult short bowel syndrome (SBS) and a Phase 3 study has been completed for NATPARA™ (recombinant human parathyroid hormone (rhPTH 1-84)) in adult hypoparathyroidism. NPS is planning to submit its U.S. marketing application for NATPARA by mid-2013. The company's earlier stage pipeline includes two clinical stage calcilytic compounds, NPSP790 and NPSP795, with potential application in the rare disorder autosomal dominant hypocalcemia and hypercalciuria (ADHH).

nps pharmaceuticals

CASE STUDY

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Overview:

The US Food and Drug Administration's denial of its New Drug Application (NDA) shoved this dynamic, young Pharmaceutical company to the brink of financial collapse. With multiple sites and a 600-person staff, they stood in a vise grip of two unforgiving realities. The company, as structured, could not afford another Phase III study. Without the study, the company itself would fail. Conventional wisdom held that the risk of failure for any clinical study is substantial even with adequate funding. The conclusion was that the company should simply close its doors.

With unshaken confidence in their company's intellectual capital, the Board of Directors stood conventional wisdom on its head. The company would focus every resource on the Phase III study but not by doing business as usual. Instead, the company would go virtual. The bulky structure of two years earlier would be stripped to the bone, leaving only a handful of essential employees to build a network of home-based employees and subcontractors. Operations that had been done internally – laboratories, manufacturing and distribution – were outsourced. Traditional concepts of what should be done were shattered by a laser commitment to what could be done. Despite its unorthodox operational structure, the company drove the study to completion and submitted the long-anticipated NDA to FDA. There was no time for celebration. The study's completion exposed gaps in the company's informal compliance and quality systems. A new deadline was set. By the time the company was audited by the FDA as part of the NDA process, the company would have an effective, compliant quality system built specifically for the company's next-generation operation.

The Solution:

Ralph Faluotico was brought on board as Vice President of Quality and handed responsibility for developing and implementing the quality system. He explained, "On May 24, the Board set a corporate goal that we would have all quality systems revamped and that everyone in the organization would be trained on them – by September 30. That gave us four months, starting from the ground up."

That starting point exposed glaring gaps. The company's 78 Standard Operating Procedures (SOPs) lacked current, accurate content reflecting the priorities and requirements of the FDA. Training was conducted by instructors in the company's conference rooms, making it unworkable for a dispersed, home-based workforce. Training was mandatory for all company personnel, including executives, but some

"Meeting the Board's goal would have been impossible without a team in which every member went beyond expectations."

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employees required training and testing on as many as 30 SOPs. There was no infrastructure to document, monitor and manage the training status of employees. Finally, there was a gap that Ralph had seen far too often at other companies. There was no system to train subcontractors throughout the quality chain, even though the company would be held accountable for any quality failure in the final product.

"I had that team in UL EduNeering, day in and day out," Ralph said. "I don't believe any other organization – certainly none I had ever seen or worked with – would have provided the same combination of expertise, shared commitment to the project or hard-driving work ethic. What we accomplished together between mid-July, when we signed the contract, and September 30, when the program officially launched, is nothing short of remarkable."

New SOPs: 78 new SOPs were written with the help of UL's Good Manufacturing Process (GMP) subject matter expert.

Training Curriculum: The training curriculum was developed based on employees and subcontractors roles. UL's GMP subject matter expert developed a customized training curriculum for NPS, incorporating 78 new SOPs. Targeted curriculum and related training assignments were designated for employees and subcontractors based on those roles.

Testing: UL's instructional design group developed test questions for each SOP, specifically designed to demonstrate the learner's knowledge and understanding of the new subject matter. All questions were completed in just three weeks.

LMS: The ComplianceWire® Learning Management System (LMS) was configured to allow targeted distribution, documentation via e-signature, monitoring and management of all training activities. The system was customized and brought online in five weeks.

System Administration: Managing the company's virtual training program was – and remains to be an outside subcontractor identified by UL. "After information is loaded into ComplianceWire about the employee's or subcontractor's role and status, our administrator can assign the required training and document all activities including the testing status for a completely compliant program," noted Ralph. "The efficiency is exceptional. I estimate that she spends less than 10 hours a month administrating the entire system."

Program Rollout: To generate employee support and confidence in the new training system, UL developed customized training guides, reference materials and communication templates for use in-house. When the program was implemented, employees were knowledgeable about the system and enthusiastic about more effective and efficient training.

Results:

"This was the most successful system implementation I'd ever been involved with, let alone a training system," said Ralph.

The company's current workforce includes 69 full-time employees, more than 30 contractors and growing sales force. "We have 100% compliance by all employees including the company's officers, who are no longer forced to sit in conference rooms according to someone else's schedule. Now, the training is online, they can take it when they have available time, and they're finished in a couple of days," explained Ralph.

Driving the Program's Success

"I can't stress enough how important service is when you're tackling a project like this under such a tight deadline," said Ralph. "UL EduNeering's partnership agreement with the FDA ensures that our content is accurate and regularly updated. The instructional designers make sure the curriculum drives learning and the testing demonstrates understanding of the new material. The program manager oversaw all the pieces and virtually forced me to set up the system right in the first place. What is most important, though, is that each one of those individuals went beyond expectations. We had four months to build and deploy a training program that could easily have taken three times that long to develop and implement. We accomplished that goal because of the service UL gave me and still gives me. I'm a strong advocate of ComplianceWire, but I'm an even stronger advocate of UL and its people."

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More About ComplianceWire

ComplianceWire is our quality-focused, fully-validated knowledge and learning management system that ensures compliance with 21 CFR Part 11 requirements. Equally valuable to Life Science companies, it supports the quality and validation constructs defined by Good Automated Manufacturing Processes (GAMPs) and GxPs, including:

- Electronic signatures and records
- Audit logs
- Record versioning
- Data security
- Fully documented SDLC
- Quality systems

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About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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