



A Culture Success Story

Program-of-the-Month vs. Real Culture Change

The Issue

The pharmaceutical industry is experiencing explosive growth and profitability, and also faces numerous challenges:

- Need for reduction of the research-to-market timeline, given growing drug development costs;
- FDA regulatory pressures that make cGMP compliance more stringent;
- Need for increased efficiency in the entire drug development cycle due to the potential impact of health care reform and managed care.

One major pharmaceutical company is under tremendous FDA pressure to bring its manufacturing division into cGMP compliance. The culture in this company is extreme “get it done” – very action oriented. The company has experienced explosive sales and market share growth of a significant product in the past five years, and manufacturing operations short-changed in budget, staffing, and training. This led to difficulties with making the significant and necessary changes to satisfy the regulatory watchdog.

Challenges

As the organization moves from highly decentralized to an integrated and centralized operation for quality and manufacturing, there are tighter reigns on independent decision making, and growing confusion about priorities and expectations. There is significant pushback, confusion, and resistance for the change, often from senior management. Employees are creative and extremely loyal to the company, but have had no training or development in leadership, teamwork, or problem solving and decision making analysis – all critical elements of the drug development and manufacturing process.

Everyone is struggling with “burnout” from a culture that constantly tries to do more with less, by yesterday. Additionally, the company is battered by significant unfavorable press about their current manufacturing woes.

The operations must radically change how it controls the manufacturing process (including testing, systems, validation, etc.), while under tremendous financial and marketplace pressures to continue “business as usual.” This will require:

- Altering daily routines that have been in place for 10-15 years,
- Creating a training organization from scratch;
- Changing the mindset on projects to include planning time;
- Involving people across functions early, to work cooperatively in the drug development and manufacturing processes.

Overarching Goals

There are two major goals for Corporate Culture Pros’s role in this project:

- Develop leadership skills for involving people in decisions and creating buy-in to a different way of working;
- Integrate a common approach for effective cross-functional teamwork and sharing of best practices, across a geographically and culturally scattered operation.

Intervention, Part One

Corporate Culture Pros began their involvement with the Quality department, which had just been separated from Manufacturing as a new reporting function to the CEO’s office.

The principle is simple: Engaging the “right minds” early in a structured planning and problem solving process leads to more efficient and higher quality decisions that are implemented more effectively. The intervention involved:

- The Corporate Culture Pros team focused first on providing skills for people to create greater buy-in and involvement, a prerequisite for successful change.
- Training a core team of approximately 30 “change agents” at the corporate level (from research and manufacturing) in Collaborative Leadership Training (a core element of CCP’s methodology) – how to utilize “visual thinking and problem solving” tools in teams to create shared understanding, alignment, and buy-in;



- Conducting targeted coaching and team building sessions with individuals and small groups;
- Rolling out the training program at the eight FDA regulated manufacturing sites, to the most senior 5-10% of the Quality leadership at each site.

Corporate Culture Pros Intervention, Part Two

The organization identified cross-functional teams across the organization whose challenge is putting new cGMP compliance standards in place and in use across the organization – world-wide this effort will touch some 20,000+ people.

Many senior leaders understand that achieving cGMP compliance is much more about creating buy-in and commitment to a common, aligned direction than about having the right technical expertise.

To jump-start team performance, Corporate Culture Pros facilitated a series of meetings to teach teams how to:

- Create and define a clear statement of a common vision and mission
- Clarify roles and responsibilities within the Site organization, especially key interfaces and decision points
- Identify specific objectives and challenges for the coming year
- Create action plans for 30-120 days
- Solidify the team
- Learn tools for gaining buy-in and commitment from the rest of the organization

The Payoff

The following comments collected from the organization's leadership indicate successful in-process measures for the way meetings and team work sessions are conducted:

- "We are accomplishing in one hour what we couldn't do in weeks of meetings"
- "We finally have meetings that are well organized and allow time for planning";
- "Our entire meeting culture has shifted in the right direction";
- "For the first time we have realistic agendas that we use";
- "The quality of our problem solving has improved",
- "After your training, we have a visual map of the entire (change) process that everyone understands, and impressed the CEO";
- "For the first time, quality and manufacturing are coordinating the widespread distribution of a common vision and action plans to accomplish them."
- "Meeting times are reduced in our area by 25-30%"
- Other signs of commitment to change, after 15 months of a 5-year process:
- Research and manufacturing are developing common commitments to the drug development process which are not mutually exclusive (as had been the case)
- Quality and manufacturing created a cohesive Training Department with a long-term strategic plan and staff for developing leadership and teamwork;
- Research has improved their "upstream" processes as they impact all other functions "downstream".

The Moral

Real change is hard.....do it before you have to.