

# Calendar of Events: November & December

November 8: Quality Management System Web Based Training  
November 15: FAC Recognition Event  
November date TBD: Manufacturing Processes Workshop

December 11: All Staff Presentation scheduling

## Q/A Resource Kit

### Current Established Communication Tools



#### Quality Management System Portal Web Site

<http://my.amgen.com/portal/>

Can be accessed from any Amgen computer.

#### EDM Teams Web Site

<http://devwww.amgen.com:9091/edmteams/>

Can be accessed by any individual in the core or management team.

#### Quality Plan Tracking System

<http://colorado.amgen.com/qpts/admin/>

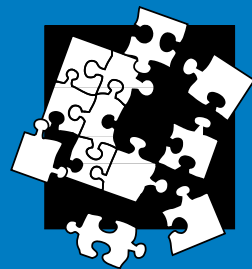
## Quality Plan Update

### Status:

- Level 2 training completed for all systems with exception of Manufacturing.
- 47% of Systems at a level 2 (Total 20 Systems)
- 55% of 20 systems require minimal work (1 deliverable & stakeholder meeting)
- Manufacturing will complete training in '06 and complete level 2 deliverables by Q1/07.

## QUA-zzle

Denise works in Department A and has an idea to improve documentation for Contractor Quality Agreements. Before submitting a proposal, she wants to do some research on how others are approaching the process elsewhere in Amgen and get feedback from the system owner. Who does Denise contact at ACO to help position her great idea to be accepted and implemented? Submit the name of who she should contact to Keith Brown in the Quality Plan Office and be entered to win a fabulous prize. Drawing will be held at the FAC event.



# The Pyramid Press

November 2006 - Inaugural Issue!

Point of Contact: Keith Brown 1-4041

## Introducing The Pyramid Press

What you're reading is the inaugural issue of the Quality Assurance Team's newsletter. We created it to provide relevant information to Amgen Colorado employees about the Quality Management System (QMS) program—how it is developing, who has successfully implemented it and how you specifically can benefit from it. It will appear electronically about every other month in your in-box and in hard-copy form in common area locations.

We named it The Pyramid Press to reflect the core concepts our pyramid logo incorporates. Elements, projects, metrics and systems. In this and future issues, you'll receive the latest news on the QA front including interviews with Amgen executives, success stories and many resources that will make your QA life easier. ■

## From the Editor's Desk

### Conditioning for the task at hand



After moving to Colorado, I started a conditioning program to acclimate to the altitude. My goal was to increase my lung capacity so that I could enjoy all the outdoor activities this great state has to offer. I quickly met that mark and promptly set another. Recently, at a higher elevation, my training program's shortcomings became clear.

While I was satisfied with my overall fitness progress, it was obvious that a long-term program was needed to continue to build my endurance and speed. So I talked to other people with experience training in Colorado and revised my plan.

It occurred to me the other day, that our Quality Management System has followed this same thought process. We created the program to help our business run more efficiently in our environment and to support the expansion of our business. And just as I called upon knowledgeable athletes to help develop my training program, our program drew upon the expertise and experience of Amgen executives and employees to create appropriate quality requirements.

But mapping out my fitness plan wasn't enough. I had to work it consistently to achieve the physical fitness I sought. It was no surprise to me that the same was true for our Quality Management System. To date, I've noticed that we are stronger in areas where we've dedicated ourselves to working the System approach. And as a result, I believe we're a stronger company and a stronger team -- one better able to take on our competition and to support our growth. ■

## What's Inside

Notes from the Boardroom.....	2
Success Spotlight.....	3
Calendar of Events.....	4
Q/A Resource Kit .....	4
Quality Plan Update .....	4
QUA-zzle.....	4

# From the Boardroom: Q&A with Martin VanTrieste, VP Commercial Quality

This month's chat with a senior executive features Martin VanTrieste, the vice president of Commercial Quality. He shared his thoughts on the Quality Management System program and its role in helping our company grow.

## What were the challenges that motivated the senior staff to implement the ACO Quality Plan Program?

**Van Trieste:** I'd say the biggest problem facing Amgen, specifically in Colorado, is our growth rate. As a company and as a site, we're experiencing exponential growth. And we expect that to continue through the next five years. That includes both the number of employees we'll have on board as well as the number of products we'll be manufacturing.

Currently we produce two products at Longmont, and our quality systems today are adequate. But as we watch our product pipeline balloon we recognize that our current systems are too complex and cumbersome to meet our future needs. And we need to do something about it before our new pipeline products enter production.

## So how would you describe the Program that grew out of that?

**Van Trieste:** Well, those realities forced us to take a hard look in the mirror and ask ourselves what we need to do differently to effectively scale our operations. It quickly became clear



Martin VanTrieste

that we need to simplify our quality systems, to streamline them, and make them far easier for people to use. That would allow us to create and implement standardized processes, based on best practices. And to do that across the company at multiple sites, not just in Colorado. We could have applied tactical Band-Aids to the problem, but it hurts when you eventually have to pull them off and apply another one. It makes much more sense to adopt a long-term strategy to integrate quality into our corporate DNA.

## In your opinion, what progress has been made to date?

**Van Trieste:** I'm impressed with the progress Ed Arling, Michele Dowling, Keith Brown, Jeff Golsan, Paul Frankel, Ben Mills, Leslie Sidor, Sherri Lewis,

and Jim Wyrwas have made to date. The Quality Management System they came up with was simple yet very robust.

The other thing is that what's been developed in Colorado is far more than what people usually think of as a traditional quality plan. It is truly a quality system. At the end of the seven-year program, we'll have a very strong quality system that has all the nuts and bolts of how to achieve the scalability and compliance goals we've set for ourselves. The Colorado team did such a nice job that we've adopted their plan as our corporate standard. Their hard work and dedication was impressive.

## Any final comments?

**Van Trieste:** Yes. I know that our colleagues in IT have been very instrumental in developing a Quality Management System Web portal. They've also created all the tools necessary to making the program successful. So I want to recognize the work of Ed Arling, Michele Dowling, Keith Brown, Jeff Golsan, Paul Frankel, Ben Mills, Leslie Sidor, Sherri Lewis, and Jim Wyrwas and thank them for a job well done. ■

## Success Spotlight



One morning not so long ago, an Amgen contractor arrived to do his work. But because his training documentation was not in order, he was locked out of the building. Frustrated by the knowledge he would have to make a second trip, the contractor resigned himself to the situation, packed up and left.

This is just one of the many time-wasting situations that the Quality Plan team seeks to eliminate. "Assigning a single point of contact for questions regarding quality for Facilities and Engineering issues has been a big step forward," said Jeff Golsan, associate manager of maintenance for Facilities & Engineering (F&E). "Previously, ownership was spread across dozens of people. One person might have been solid while another had gaps in their handling. Having a single owner accountable for their results has significantly improved the way we do business."

Golsan notes that this change was an essential step to migrate away from people-based procedures to a more systemic, process-based approach. "That's the kind of change we're trying to affect in the F&E organization because it's much

## Facilities & Engineering achieving measurable results for QP efforts

*"A systemic approach to Quality Management prevents a lot of reworking. If a procedure is documented clearly, then a user can make a decision based on that. If not, they have to go back to the person who wrote it for clarification. Fixing system issues to improve efficiency is the gist of the Quality Management System approach."*

- Jeff Golsan, Associate Manager of Maintenance, Facilities & Engineering

more efficient. By improving our processes for contractor documentation, for example, we'll be able to prevent wasteful happenings like the contractor being locked out of the building."

Already, the F&E Quality Plan team has achieved measurable results for their efforts. Recently, his staff completed an audit of their GMP training. "Using the quality plan approach, our audit showed that our compliance rating was in the 60 to 70 percent range," explained Golsan. "Improving that became an action item for Jim Archbold on my staff. After correcting some of the gaps we identified, Jim increased our compliance to over 90 percent within six weeks."

The F&E Quality Plan team was able to leverage the lessons learned from that experience by working with the training department to develop some best practices. "Now, if other departments need to perform key audits, we can help them. That's a key advantage of the peer-to-peer interaction we can provide."

Another F&E Quality Plan system involves proactive pest control at the ACO site. The F&E Quality Plan team has been working to revise the SOP manual, a core function of the system. They identified gaps in how their contractors execute their duties and document their training. "As a result, we'll shortly have a better, more robust procedure governing our contractor pest control inspection activities. We've also taken measures to improve the accuracy of the data we get from our pest control vendors and Amgen staff." ■