The History and Future of the Quality Unit in Pharmaceutical Manufacturing:

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The Quality Department is the cornerstone for our success.
We are facing rapid change in our industry.
How will these changes affect the quality unit?
To help predict forward, we will take a brief look backward.
Then we will look at some current trends impacting our organization.
The organization of the quality unit has evolved over time.
Earliest industrial history was the artisan in the one-person shop.
As shops grew, the job of a full-time “inspector” developed.
Quality Departments supervised by Chief Inspectors formed in the 1920’s.
Quality engineering and statistical quality control developed in the 1940’s.
Reliability engineering became popular in the 1950’s.
The pharmaceutical GMP’s had a significant impact on the quality unit.

Good Manufacturing Practices
21 CFR 210
21 CFR 211

As Published in the Federal Register
Revision Date: April 1, 1998
In the pharma industry, the quality approach was different.
The quality unit has broad responsibilities defined in the regulation.
The organizational structure of the Quality Department is not mandated.

- QA reports to a general manager at the plant site
- Site QA directly reports to a general manager at the site but has a strong dotted line to a central QA organization
- Plant QA reports to a central QA organization geographically separated
There has been little emphasis on quality science.
There are Pros and Cons of the Standard Pharma Quality Unit Design.
The organizational independence of the quality unit is a trade off.
Some current and future trends for quality organizations are evident.

- Quality System Regulations
- Process Analytical Technology (PAT)
- 100% Inspection Programs
- Design Space
- Quality Science
- Quality Management Teams
The quality systems approach is under discussion.
Quality Management Teams (QMT) help build a quality culture.

- Comprised of General Manager and Staff
- Meet Monthly
- Review Quality Trends
- Discuss Quality Problems
- Select Quality Improvement Projects

Ensure all Departments are Working Together

- Fully Integrates the Quality Department with the rest of the plant
- Excellent Forum for Developing and Updating the Quality Plan
LIMS systems become more powerful and integrated.
Electronic Laboratory Notebooks eliminate tedious manual entries.
PAT reduces manual testing.
Risk based management changes the way we think.

ICH - Q9
Product Quality Research Institute - (PQRI)
Risk Management Work Group
FDA Guidance Documents
100% inspection programs improve our process knowledge.

- Metal Check Devices
- Automatic Weigh Check
- Thickness Sorters
- Vision Inspection Systems
- Detectors: e.g. Caps, Seals
  Empty Bottles
Will we be able to make the transition to the new quality paradigm?
The pharmaceutical industry is undergoing rapid change.

What will the Quality Unit of the Future Look Like?

More focus on Statistical Process Control and Reliability Engineering?
More automation and less manual work (less chemists and more PCS Technicians?)
Greater need for professional team facilitators, trainers, project managers?

Application of Quality Science
Less need for lab space
More 100% Inspection
Greater IT System Integration
How will these changes affect the quality unit?
A QA unit that does not adapt to change will rapidly fall behind.

“If you want to get somewhere else, you must run at least twice as fast as that!”

*Lewis Carrol*
References:


