

# ***KEMIA CONSULTANTS***



***ENGINEERING SOLUTIONS  
FOR THE 21<sup>ST</sup> CENTURY***

***KAUKO H. AUNIO***

***PRESIDENT***

***78 CHRISTIAN HILL RD.***

***AMHERST, NH 03031***

***KAUNIO@COMCAST.NET***

***WWW.KEMIACONSULTANTS.COM***

***732-397-0516***

# Design Control

Presentation to the American Society of  
Quality

# Design Control

## ▶ Medical Device

- Compliance with FDA Regulations (21 CFR 820)
  - Installation Qualification (820.75)
  - Operational Qualification (820.75)
  - Production Qualification (820.75)
  - Biocompatibility (ISO-10993, FDA Consensus Standard)
- Compliance with FDA Audits (FDA Form 482)
- Compliance with Internal Requirements / Procedures (820.5)

# Design Control

- ▶ The Real Issue is the Design Itself
  - Concept and Need
  - Research and Development
  - Detailed Design
  - Prototype
  - Testing
  - Clinical Testing
  - Involvement of the Physicians
  - Biological Testing

# Design Control

- ▶ Chemical Industry
  - Engineering Standards
    - ASME, NFPA, ASHREA and ANSI
    - Internal Standards
    - Technology Standards
    - Design Standards
      - Trip/Alarm
      - Venting
      - Conditioning
      - Work Permits

# Design Control

- ▶ Design Process
  - Concept and Need
  - Research and Development
  - Detailed Design
  - Design Review
  - Construction
  - Commissioning
  - Operation

# Design Control

- ▶ Cross Functional Design Review
  - Very powerful tool
  - Involvement of the key players
    - Design Engineer
    - Senior Engineer
    - Control Engineer
    - Maintenance Representative
  - Detailed review of the design

# Design Control

- ▶ HAZOP – Hazard and Operability Studies
  - Trained Leader
  - Leader not Involved in the Design or the Project
  - Total of Six Systematic and Integrated Studies
  - For Large Projects – New Plant, Introduction of a New Product, May Want to Consider the Full Process
  - Smaller Projects Require Only Hazard Study 3



# Design Control

- ▶ Hazard Study 1
  - Completed at a Very Early Stage of the Project
  - Identify the Safety, Health and Environmental Issues
  - Provides Information for the Environmental Impact Statement
  - Discuss what Further Hazard Studies will be Required

# Design Control

- ▶ Hazard Study 2
  - Carried Out at the Conceptual Stage
  - Identifies the Hazards in Terms of Fire, Explosion and Toxic Release
  - Identify what Control Features Need to be Included in the Design
  - Alarm and Trip Systems Considered
  - Plant and Equipment Identified

# Design Control

- ▶ Hazard Study 3
  - Review of the Firm Design
  - Requires Cross Functional Team
  - Identify Hazard and Operability Problems
  - Can also Consider:
    - Relief and Blowdown Studies
    - Area Classification
    - Personnel Protection
    - Manual Handling

# Design Control

- ▶ Hazard Study 4
  - Construction Complete
  - Prior to the Start of Commissioning
  - Review to Ensure the Actions from the Detailed Hazard Study have been Completed
  - Check operating procedures
  - Check Emergency Procedures

# Design Control

- ▶ Hazard Study 5
  - Completed Prior to Start-Up
  - Covers:
    - Training
    - Review of Operating Procedures
    - Start-Up Preparation
    - Readiness for Start-Up (Function Testing, Cleanliness and Purging)
  - Confirmation of Compliance with Company and Legislative Standards

# Design Control

- ▶ Hazard Study 6
  - Carried Out Several Months After Start-Up
  - Complete Check to see if All the Actions from the Previous Studies are Complete
  - Identify any new Lessons Learned that can Benefit Future Design Work
  - Confirms that the Actual Operation meets all Safety and Health Requirements

# Design Of Experiments

Presentation to the American Society of Quality

- Fluoropolymer Manufacture
  - Very Complex and Difficult
  - High Hazard – TFE Monomer is Flammable and Explosive
  - Requires High Purity Water
  - Requires High Purity Monomer
  - The Polymerization is Total Fluorine System – no Hydrocarbons
  - The Final Product is White and Must be Kept Very Clean

## Design of Experiments



- Fluoropolymer Plant
  - Bayonne, New Jersey
  - Team:
    - Research and Development
    - Process Engineering
    - Surfactant Chemistry
    - Polymerization Expertise
    - Distillation Expertise
    - Polymer Processing Expertise
    - Technical Service
    - Product Stewardship

## Design of Experiments

- Compounding Plant
  - Utilizes Granular PTFE Resin in Compounding
  - Resins are Used for Seals, Piston Rings, etc.
  - Six Sigma Operation
  - Proprietary Technology
  - Utilizes Surfactant Technology
  - Sales to the Automotive Market and Appliances
  - Continuous Drying

## Design of Experiments

- Compounding Plant
  - Thorndale, PA
  - Team
    - Research and Development
    - Compounding Technology
    - Color Matching
    - Wear Resistance
    - Polymer Processing
    - Surfactant Technology
    - Knowledge of Fillers

## Design of Experiments

- How do you manage design of experiments with complex technology?
  - What did I ask the group to do?
    - Think!
    - You know the chemistry
    - Research the past – past studies, experiments reports, etc.
    - Review the current quality data and long term trends
    - Study the system design and services

## Design of Experiments

- Plan your approach
  - Look at your matrix
  - Think about the sequence of experiments – which will give you the most information
    - Extreme experiments?
    - Experiments focused on current operation?
  - Run the experiments
  - Collect the data and review
  - Determine what direction you wish to go

# Design of Experiments

- What was the result?
  - Most experimental programs were successful in gathering the data required with fewer experiments
  - Most of these programs were run more quickly
  - It is not possible to reduce the experimentation across the board – sometime you have to compete the entire experimental program
  - In the interest of reducing effort and using your time more efficiently, one should always challenge the norm

## Design of Experiments

**KEMIA CONSULTANTS**    Engineering Solutions for the 21st Century

**Services**

Technology Development

Process Development

Product Development – Research

Process Optimization

Process Design

Design Control – HAZOP

Design of Experiments

Specification Development

Troubleshooting