BTEC 101

Standard Operating Procedures
SOPs

SOP Topics

- Why they are needed
- What types must be created
- Which signatures are required on an SOP
- What major sections are contained within SOPs
- Why they are controlled documents
- How they are controlled

SOPs – Why they are needed

- SOPs are needed to assure consistent manufacturing of high quality product meeting predetermined specifications.
- SOPs provide **detailed, step-by-step instructions** for personnel working in:
  - Facilities
  - QC (Quality Control)
  - QA (Quality Assurance)
  - Production

Example of why SOPs are Necessary

One instruction states "Shake vial until thoroughly mixed"

- How would you shake it? And you?
- What other ways are there to shake something?
- Would the results be the same?
- Which method is the best?

Why are SOPs Needed?

- Biotechnology production requires **controlled** operating conditions
- Conditions to be maintained/controlled include **critical** parameters (conditions)
- SOPs should never allow for ambiguity–
- The procedure should state **clearly** how to perform the operation

Purification Example

Purification is necessary to purify the product away from contamination.

- Uses combination of isolation techniques, sampling & cleaning procedures to assure product quality.
- Mistakes can threaten the health of the consumer.
- So critical processes such as production, testing, sampling, & equipment cleaning must be consistent.

SOP Expectations

- Kept at location task is performed – **What** about e-versions?
- Consulted "frequently"!
- Memorization not a substitute for referring – **Why**?
- Personnel must be retrained on the latest versions of the document.

Many organizations subdivide their SOPs into categories based upon their purpose.

Even a company producing just one product can have several hundred SOPs

Strongly Enforced by the FDA

- Failing to follow a written procedure is considered a compliance violation.
- Could the company receive a 483 for this?
- **What** is the worst that can result from not following an SOP?

What Types of SOPs Must be Created
Title 21 CFR Section 211

States we must create written procedures (SOPs) which describe:

- Equipment cleaning & maintenance
- The storage, handling & testing of raw materials
- Production & process controls
- Sampling & testing of in-process materials
- Methods for controlling microbiological contamination

Types of SOPs

- Equipment cleaning
- Equipment calibration, preventive maintenance, validation
- Material storage & handling
- Drafting & revising of **all** controlled documents

All procedures to assure compliance require SOPs

Types of SOPs

- Administrative Ex:_____
- Operations
- Facilities
- Quality Control
- Standard Manufacturing Procedures
- Safety
- Quality Assurance

SOPs Contain:

- Company name, confidential & proprietary, revision number & page number (X of Y)
- Effective date & name of the person who wrote the document
- Approval signatures:
  - The author's department
  - ***Quality Assurance*** – always!!
  - Departments directly involved, these depend upon the particular SOP

SOP Major Sections Which Must be Included

- Purpose
- Scope
- Responsibility
- References
- Definitions
- Safety
- Procedure
- Attachments

SOP Standard Practices

All sections are numbered consequtively

If a particular section is not relevant, then **N/A** is placed next to that particular section

What does that “N/A” indicate to the person following the SOP?

SOPs are Controlled Documents

Each SOP has a **unique** number.

What does this unique number allow us/FDA to do?

Control of SOPs

Issuing of SOPs

-When new or changed procedure

-Whenever SOP is revised

-There is a procedure for this process that most companies follow

Issuing of SOPs

- Unique number/version is assigned
- Draft circulated & reviewed
- Approved & signed
- Effective date assigned
- Training of users
- Documents become effective
- Distributed to users

Recalling of Obsolete Documents

- Once a revised SOP has been issued, the previous document becomes **obsolete**.

These obsolete documents are recalled by QA, why?

The master is stored & the copies are shredded.

Current Example of SOP Non-compliance

SOP Topics – Verbal Review

- Why are SOPs needed?
- Name two types which must be created
- Which signature is always required on an SOP?
- Name three major sections contained within SOPs
- Why are SOPs controlled?