CASE STUDY | PHARMA BIOTECH

REVIEW OF QUALITY SYSTEM SOPS

by Andy Barnett

CLIENT:

Large international pharmaceutical manufacturer.

SITUATION:

NSF's client requested a proactive review of major quality systems and procedures in response to a warning letter.

SOLUTION:

NSF reviewed and critiqued essential quality systems SOPs against regulatory standards and industry best practices. This included sampling plans, CAPAs, risk assessment, calibration, preventive maintenance, etc. We verified that actual practice complied with SOP commitments and remediated as necessary.

FINDINGS:

Risk Assessment SOP

We discovered this particular SOP had an error in the risk scoring definitions for detectability. The "as found" definitions and risk scoring grid were:

Severity x Frequency				
	9	9	18	27
	8	8	16	24
	7	7	14	21
	6	6	12	18
	5	5	10	15
	4	4	8	12
	3	3	6	9
	2	2	4	6
	1	1	2	3
		1	2	3
		Detectability		

DETECTABILITY:

VALUE	P: Probability
1	High: No mechanism for detection
2	Medium: May be detected at a later stage
3	Low: Will be detected immediately

The definitions for detectability were reversed! High-risk items were given a low score and low-risk items were given a high score. 14 of the 27 scoring combinations were affected, resulting in incorrect evaluation of overall risk.

BENEFITS TO CLIENT:

The SOP was fixed. The company performed a retrospective review of management review/ prioritization decisions, focusing on items that had low overall risk, but should have been high. Once the SOP was fixed, the company properly prioritized all risk-based events.

For more information, contact **pharmamail@nsf.org** or visit **www.nsfpharmabiotech.org**

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