Quality Assurance: Problem Solving and Training Strategies for Success in the Pharmaceutical and Life Science Industries (Woodhead Publishing Series in Biomedicine)

G Welty

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Quality assurance is necessary to maintain quality and services in the pharmaceutical and life science industries. Quality assurance demonstrates that the logic and practice of problem solving can integrate both program efficacy and regulatory compliance. This title is divided into three parts; the first part discusses the process by which a problem in regulated industry is identified, for example a manufacturing deviation that leads to an adulterated drug product, and reviews the decision-making steps involved in remedying the problem. The second part delves into the staff training requirements of procedures that are thereby revised. The third part expands on this discussion by considering piloting the proposed training module, preparing assessments of trainee proficiency, evaluating the training module, including integrating rigorous evaluative designs with formative program improvement, and documenting the entire effort.

• Presents a comprehensive view of the field of quality assurance
• An approach grounded in direct experience
• Uses diagrams and figures to clarify analytical points

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