Audit #: _____ Auditor(s): _____ Date: _____

Quality System – ICH Q10	Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:	Conforms to Requirements
Is the Quality Manual current with respect to processes and procedures and available at all times to employees?		☐ Yes ☐ No
Has management established a quality policy and has it been signed by upper management?		☐ Yes ☐ No
Have Quality objectives been established at all relevant levels to reflect the principals of ICH-10 and performance against these objectives measured and reviewed?		☐ Yes ☐ No
Are there adequate resources (human, financial, materials, facilities and equipment) provided to implement, maintain and improve the quality system?		☐ Yes ☐ No
Do internal communications assure the flow of appropriate information (in both directions) between all levels of the company?		☐ Yes ☐ No
Are periodic reviews of the quality system, process performance and product quality conducted, with documented completion of any identified follow-up actions?		☐ Yes ☐ No
Does the use of outsources activities and/or purchase materials include: appropriate use of quality risk management; defined and documented evaluation and selection process; documented quality agreement defining respective responsibilities or specifications; and monitoring and review of supplier/subcontractor performance?		☐ Yes ☐ No
Is there a defined control strategy for both process performance and product quality, and does this strategy incorporate appropriate quality risk management principals and techniques?		☐ Yes ☐ No

Have appropriate data management and statistical tools been provided to implement the control strategy. Are these tools implemented and results evaluated to improve process and product performance?		☐ Yes ☐ No
Is there a formal corrective and preventive action (CAPA) system to capture input from various sources (e.g. complaints, product rejections, process deviations, recalls, audits, process/product data trends, OOS, management reviews, etc.) and assure follow-up CAPA actions (including measuring the effectiveness of completed actions)?		☐ Yes ☐ No
Is there a defined and documented focus on continual improvement of the quality management system?		☐ Yes ☐ No