

Concentration: Regulatory Affairs and Clinical Trails

JUNE 8, 2000

CRITICAL WORK FUNCTIONS	KEY ACTIVITIES									
A. Support clinical research	A1 Perform record keeping	A2 Assist with and coordinate development of clinical trial support documents	A3 Research current literature regarding clinical trials	A4 Report on status of clinical trials	A5 Facilitate communication with IRB	A6 Monitor clinical sites	A7 Assist with study drug management	A8 Review data from clinical trials		
B. Review, process and communicate data	B1 Record and organize data	B2 Conduct simple analyses of data and product information	B3 Flag problems and issues	B4 Track approvals and renewals	B5 Draft reports					
C. Coordinate with manufacturing and other departments regarding regulatory and compliance practices	C1 Prepare updates on laws, regulations and guidelines for distribution to company personnel	C2 Monitor and evaluate manufacturing process changes	C3 Review data and reports for compliance	C4 Assist in maintenance of document control system	C5 Conduct audits	C6 Review promotional media to ensure compliance	C7 Support quality assurance	C8 Assist in training programs	C9 Assist with resolution of quality issues	
D. Participate in interactions with regulatory agencies	D1 Perform literature searches	D2 Assist with submission preparation and with international documents and licenses	D3 Assist with regulatory document control	D4 Assist with preparation for FDA meetings	D5 Keep current on regulatory requirements	D6 Assist with inspections and audits from regulatory agencies				

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – A. Support clinical research

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS skills and foundational abilities</i>
A1. Perform record keeping	<ul style="list-style-type: none"> ■ Data forms are complete, accurate, legible and are completed in a timely manner. ■ Data integrity is maintained. ■ Data entry is accurate and timely. ■ Data are retrievable. ■ Record keeping is completed in compliance with company procedures and regulatory requirements. 	<ul style="list-style-type: none"> ■ Knowledge of regulatory agency requirements regarding record keeping. ■ Knowledge of company procedures regarding record keeping. ■ Knowledge of company filing system. 	<ul style="list-style-type: none"> ■ Records information accurately, completes documentation, and summarizes information. ■ Examines information/data for relevance and accuracy. ■ Understands computer operations, utilizes integrated/multiple software, locates and retrieves information/data and utilizes networks ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.
A2. Assist with and coordinate development of clinical trial support documents	<ul style="list-style-type: none"> ■ All documents are available to appropriate personnel. ■ Revision control is maintained. ■ Case report forms accurately reflect protocol requirements. ■ Support documents are accurately prepared and assembled. ■ Site documents are provided to sponsor according to prescribed timelines. 	<ul style="list-style-type: none"> ■ Knowledge of document filing system and location. ■ Knowledge of revision control techniques. ■ Ability to prepare support documents. ■ Knowledge of Code of Federal Regulations (CFR). ■ Knowledge of site documents and the ability to locate timelines and sponsor addresses. 	<ul style="list-style-type: none"> ■ Analyzes organization of information and transfers information between formats. ■ Examines information/data for relevance and accuracy. ■ Prepares basic summaries and reports. ■ Performs given set of tasks and follows schedules.
A3. Research current literature regarding clinical trials	<ul style="list-style-type: none"> ■ Research is pertinent to the assigned topic. ■ Research includes bibliography. ■ Research is complete and accurate in accordance with request. 	<ul style="list-style-type: none"> ■ Knowledge of the topic. ■ Knowledge of current literature sources. ■ Knowledge of Web and electronic search techniques. 	<ul style="list-style-type: none"> ■ Understands computer operations, utilizes integrated/multiple software, locates and retrieves information/data, and utilizes networks. ■ Identifies data/information, analyzes it, and integrates multiple items of data. ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details.
A4. Report on status of clinical trials	<ul style="list-style-type: none"> ■ Report is completed in a timely manner. ■ Report is well organized and includes a logical flow of information. ■ Report includes an executive summary. ■ The report includes assessment of protocol. ■ The report is complete and accurate. ■ The report includes issues and flags problems. ■ The report is grammatically correct and uses the proper format. 	<ul style="list-style-type: none"> ■ Knowledge of protocol assessment. ■ Ability to identify problems and issues. ■ Knowledge of medical and industry terminology, jargon, and acronyms. 	<ul style="list-style-type: none"> ■ Performs given set of tasks and follows schedules. ■ Summarizes/paraphrases information and creates original documents. ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Examines information/data for relevance and accuracy

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Critical Work Function – A. Support clinical research

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A5. Facilitate communication with IRB	<ul style="list-style-type: none"> ■ Adverse events are forwarded to IRB. ■ Protocols are approved by IRB prior to study initiation. ■ All communication is documented in accordance with company policy. ■ IRB meetings are communicated to appropriate personnel. ■ Draft responses are complete and prepared in a timely manner and are submitted for internal review. ■ Copies of IRB correspondence are retained and organized in a retrievable manner. 	<ul style="list-style-type: none"> ■ Ability to identify reportable adverse events using clinical site reports and protocols (case report forms). ■ Knowledge of medical industry terminology and jargon. ■ Ability to locate IRB approvals. ■ Knowledge of IRB meetings. ■ Knowledge of roles of personnel. ■ Knowledge of regulatory agency requirements. ■ Knowledge of filing system. ■ Knowledge of protocol requirements. 	<ul style="list-style-type: none"> ■ Demonstrates commitment to social improvement, analyzes implications of decisions, and recommends ethical courses of action. ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Records information accurately, completes documentation, and summarizes information. ■ Summarizes/paraphrases information and creates original documents. ■ Presents basic ideas/information. ■ Understands system organization and follows processes and procedures.
A6. Monitor clinical sites	<ul style="list-style-type: none"> ■ Clinical site is verified as having required documents and records. ■ Site documents and records reflect the requirements defined in the contract and the protocols. ■ Clinical sites are monitored in accordance with established schedule. ■ Written report documenting the site visit is prepared in a timely manner and is complete and accurate. ■ Site is monitored for informed consent records, patient data forms, adherence to protocols, and IRB approval of changes. 	<ul style="list-style-type: none"> ■ Knowledge of required documents and records. ■ Ability to interpret contracts and protocols. ■ Knowledge of medical and industry terminology, jargon, and acronyms. ■ Knowledge of contents of site visit reports. ■ Knowledge of proper completion of informed consent records and patient data forms. ■ Knowledge of protocols and IRB approvals. ■ Ability to identify reportable adverse events from patient data forms. 	<ul style="list-style-type: none"> ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Applies principles to processes/procedures and uses logic to draw conclusions. ■ Performs given set of tasks and follows schedules. ■ Records information accurately, summarizes/paraphrases information, and creates original documents. ■ Collects data and identifies discrepancies.
A7. Assist with study drug and device management	<ul style="list-style-type: none"> ■ Correct storage and labeling of study drug are confirmed. ■ Study drugs and device management are accurately counted and reconciled to previous inventory. ■ Storage, labeling, and counts are properly documented. 	<ul style="list-style-type: none"> ■ Knowledge of study drug and device labeling and storage procedures. ■ Knowledge of documentation procedures. ■ Knowledge of protocols and 21 CFR 312. ■ Ability to locate storage facility. ■ Knowledge of how environmental conditions are controlled, maintained, and documented. ■ Ability to reconcile the devices used against inventory. 	<ul style="list-style-type: none"> ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Obtains data, performs measurements, and converts numerical data. ■ Records information accurately, completes documentation, and summarizes information.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – A. Support clinical research

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<p>A8. Review data from clinical trials</p>	<ul style="list-style-type: none"> ■ Missing data are identified and sites are contacted for explanation of any missing data. ■ Source documentation is compared with database print-out to verify accuracy ■ Source documentation is reviewed for credibility and data integrity. 	<ul style="list-style-type: none"> ■ Knowledge of data requirements of clinical trial. ■ Ability to obtain source documentation from multiple departments and files. ■ Knowledge of contents of source documentation ■ Knowledge of hazardous material handling and disposal procedures and laws. 	<ul style="list-style-type: none"> ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Examines information/data for relevance and accuracy. ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Responds to verbal/nonverbal communication and confirms information.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – B. Review, process, and communicate data

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS skills and foundational abilities</i>
B1. Record and organize data	<ul style="list-style-type: none"> ■ Data is accurately compiled and formatted in accordance with assignment. ■ Record and format are legible. ■ Data is properly organized and categorized. 	<ul style="list-style-type: none"> ■ Knowledge of data formats and recording procedures. ■ Ability to perform searches on regulatory agency databases in order to compile data. ■ Knowledge of data categories and purpose. 	<ul style="list-style-type: none"> ■ Analyzes organization of information and transfers information between formats. ■ Summarizes/integrates information. ■ Records information accurately, completes documentation, and summarizes information. ■ Analyzes data and integrates multiple items of data. ■ Examines information/data for relevance and accuracy.
B2. Conduct simple analyses of data and process information	<ul style="list-style-type: none"> ■ Mathematical formulae are correctly selected and applied. ■ Correct data set is used. ■ Calculations are properly documented. ■ Data integrity is preserved. ■ Out-of-range or out-of-specification results are identified. ■ Trends are identified. 	<ul style="list-style-type: none"> ■ Ability to match the correct mathematical formula with the purpose of the analysis. ■ Ability to identify data sets and match them to the analysis being performed. ■ Knowledge of documentation procedures. ■ Ability to identify out-of-range or out-of-specification results. ■ Knowledge of the goals and components of the study being analyzed. 	<ul style="list-style-type: none"> ■ Manipulates techniques/formulas/processes and interprets mathematical data. ■ Selects/obtains data relevant to the task and identifies the need for data. ■ Converts numerical data and predicts arithmetic results.
B3. Flag problems and issues	<ul style="list-style-type: none"> ■ Out-of-range or out-of-specification results are identified. ■ Errors are identified, documented, and reported to supervisor. ■ Questionable data integrity is identified and reported to supervisor. 	<ul style="list-style-type: none"> ■ Ability to identify out-of-range or out-of-specification results. ■ Knowledge of basic probability and statistics. ■ Knowledge of eligibility requirements of data. 	<ul style="list-style-type: none"> ■ Converts numerical data and predicts arithmetic results. ■ Examines information/data for relevance and accuracy.
B4. Track approvals and renewals	<ul style="list-style-type: none"> ■ Permits are renewed prior to expiration dates. ■ Regulatory agency required reports are prepared for submission prior to due date in accordance with company formats. ■ Upcoming due dates are anticipated and communicated to other departments in a timely manner. ■ Sources are consulted to keep current on new drug, devices, and biological approvals, and results are effectively communicated to appropriate personnel and departments. 	<ul style="list-style-type: none"> ■ Ability to locate permits. ■ Knowledge of regulatory agency requirements. ■ Knowledge of company formats. ■ Knowledge of roles of departments and the approvals they require. ■ Knowledge of sources of information for new drug, devices, and biological approvals. ■ Knowledge of industry terminology, jargon, and acronyms. 	<ul style="list-style-type: none"> ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Writes simple documents. ■ Recognizes patterns/relationships. ■ Uses previous training/experience to predict outcomes. ■ Presents complete ideas/information and poses critical questions. ■ Probes to gain knowledge/information, qualifies/analyzes information and interprets and summarizes information.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – B. Review, process, and communicate data

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B5. Draft reports	<ul style="list-style-type: none"> ■ Report is completed in a timely manner. ■ Report is well organized and includes a logical flow of information. ■ The report is complete and accurate. ■ The report includes issues and flags problems. ■ The report is grammatically correct and uses the proper format. ■ The report is formatted in accordance with regulatory agency preferences. 	<ul style="list-style-type: none"> ■ Knowledge of the contents required in the report. ■ Ability to identify issues and problems. ■ Knowledge of industry terminology, jargon, and acronyms. ■ Knowledge of regulatory agency preferred formatting and structure. ■ Knowledge of technical writing. 	<ul style="list-style-type: none"> ■ Records information accurately, summarizes/paraphrases information, and creates original documents. ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Examines information/data for relevance and accuracy. ■ Applies principles to process/procedure and uses logic to draw conclusions.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – C. Communicate with manufacturing and other departments regarding regulatory and compliance practices

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS skills and foundational abilities</i>
C1. Prepare updates on laws, regulations, and guidelines for distribution to company personnel	<ul style="list-style-type: none"> ■ Sources for regulatory updates and proposals are thoroughly reviewed. ■ A variety of sources and media are searched. ■ Appropriate personnel are informed effectively and in a timely manner. ■ Updates are prepared and issued in accordance with company policies and procedures. ■ FOI sources are regularly contacted for pertinent updates in a timely manner. 	<ul style="list-style-type: none"> ■ Knowledge of laws, regulations, and guidelines. ■ Knowledge of sources of media. ■ Knowledge of company policies and procedures regarding updates. ■ Knowledge of FOI sources and how to contact them. 	<ul style="list-style-type: none"> ■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information. ■ Examines information/data for relevance and accuracy. ■ Presents basic ideas/information. ■ Records information accurately, summarizes/paraphrases information, and creates original documents. ■ Confirms information.
C2. Monitor and evaluate design and manufacturing process changes	<ul style="list-style-type: none"> ■ Manufacturing design and process changes are identified and categorized. ■ Design and process changes are sent to the appropriate regulatory body. ■ Design and manufacturing process changes are assessed against regulatory commitments, and results are reported to supervisor. ■ Documentation of review is properly completed. 	<ul style="list-style-type: none"> ■ Knowledge of design and manufacturing process changes. ■ Knowledge of categories of change. ■ Knowledge of regulatory commitments. ■ Knowledge of documentation procedures. 	<ul style="list-style-type: none"> ■ Applies principles to processes/procedures and uses logic to draw conclusions. ■ Analyzes situation/information, considers risks/implications, and compiles multiple viewpoints. ■ Examines information/data and recommends action plan. ■ Develops creative solutions. ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Demonstrates commitment to social improvement, analyzes implications of decisions, and recommends ethical courses of action.
C3. Review data and reports for compliance	<ul style="list-style-type: none"> ■ Documentation standards are thoroughly checked against requirements. ■ Data referenced in support of conclusions is checked for completeness, relevance, and accuracy. ■ Outcome of review is communicated to the report author or supervisor as required. ■ Calculations are audited for accuracy. ■ Reports and data are reviewed to ensure they are complete and in compliance with regulations. 	<ul style="list-style-type: none"> ■ Ability to interpret and assess production records. ■ Ability to assess the adequacy of validation reports. ■ Knowledge of regulations. ■ Knowledge of documentation standards. ■ Knowledge of validation report requirements. 	<ul style="list-style-type: none"> ■ Adheres to standards. ■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details. ■ Applies principles to processes/procedures and uses logic to draw conclusions. ■ Presents complex ideas/information and poses critical questions. ■ Manipulates techniques/formulas/processes and interprets mathematical data. ■ Predicts arithmetic results. ■ Identifies relevant details, facts and specifications, qualifies information, and interprets and summarizes information.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – C. Communicate with manufacturing and other departments regarding regulatory and compliance practices

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS skills and foundational abilities</i>
C4. Assist in maintenance of document control system	<ul style="list-style-type: none"> ■ Documents are prepared and distributed in accordance with company policies and procedures. ■ The latest version of the document reflects the most current revision, and is distributed in a timely manner. ■ Distribution lists are kept current and accurate. ■ Copies of outdated versions are retrieved and destroyed in accordance with company policies and procedures. ■ Previous original document versions are properly archived. ■ All security measures and rules are followed. 	<ul style="list-style-type: none"> ■ Knowledge of company policies and procedures regarding document preparation, distribution, and disposal. ■ Ability to locate and identify the most current revision. ■ Ability to obtain distribution lists. ■ Ability to retrieve outdated versions. ■ Knowledge of archiving procedures. ■ Knowledge of security rules and measures. 	<ul style="list-style-type: none"> ■ Sets well defined/realistic goals. ■ Manages timelines and recommends timeline adjustments. ■ Examines information/data for relevance and accuracy. ■ Performs assigned task, follows rules/policies/procedures, and pays attention to details. ■ Recognizes ethical issues and demonstrates trustworthiness.
C5. Conduct audits	<ul style="list-style-type: none"> ■ Company audit procedures are followed. ■ Findings and reports are clearly documented. ■ Issues are communicated to and followed up with departments and personnel audited. ■ Audit results are communicated to appropriate personnel effectively and in a timely manner. ■ Audit reports contain correct grammar, appropriate format, and use neutral language. ■ Findings are specific, functional, descriptive and non-editorial. 	<ul style="list-style-type: none"> ■ Knowledge of company audit procedures. ■ Knowledge of documentation procedures. ■ Ability to identify issues which need follow-up. ■ Knowledge of contents of audit reports. ■ Knowledge of audit interviewing techniques. ■ Knowledge of regulatory agency requirements. ■ Knowledge of CFR references. ■ Knowledge of how to document a finding and reference it. 	<ul style="list-style-type: none"> ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Records information accurately, summarizes/paraphrases information, and creates original documents and technical reports. ■ Presents complex ideas/information and poses critical questions. ■ Examines information/data, analyzes possible causes/reasons and recommends action plan. ■ Analyzes situation/information, considers risks/implications, and compiles multiple viewpoints. ■ Demonstrates commitment to social improvement, analyzes implications of decisions, and recommends ethical courses of action.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – C. Communicate with manufacturing and other departments regarding regulatory and compliance practices

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<p>C6. Review promotional media to ensure compliance</p>	<ul style="list-style-type: none"> ■ Promotional piece artwork and copy are compared to the approved specification. ■ Errors are identified and communicated to appropriate personnel effectively and in a timely manner. ■ Claims for the product are reviewed to ensure they match with approved use. ■ Results of review and all approvals and rejections are properly documented and communicated to appropriate personnel. ■ Original documents are properly archived. ■ Final copies of promotional media are sent to the FDA in accordance with regulatory agency requirements or requests for labeling. 	<ul style="list-style-type: none"> ■ Knowledge of approved specifications. ■ Knowledge of approved use. ■ Knowledge of documentation procedures for reviews, approvals, and rejections. ■ Knowledge of archiving procedures. ■ Knowledge of regulatory agency requirements. 	<ul style="list-style-type: none"> ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Presents complex ideas/information and poses critical questions. ■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information. ■ Records information accurately, summarizes/paraphrases information, and creates original documents. ■ Examines information/data for relevance and accuracy.
<p>C7. Support quality assurance</p>	<ul style="list-style-type: none"> ■ QA processes and reports are reviewed or audited to ensure they are in compliance with internal procedures and regulatory requirements. ■ QA generated data is reviewed for compliance with regulatory filings or commitments. ■ Regulatory requirements are interpreted and communicated to appropriate QA personnel. ■ Quality System is followed and continuous improvement suggestions are made. 	<ul style="list-style-type: none"> ■ Knowledge of QA processes. ■ Knowledge of internal procedures and regulatory requirements. ■ Knowledge of regulatory filings and commitments. ■ Ability to interpret regulatory requirements. ■ Knowledge of Quality Systems. 	<ul style="list-style-type: none"> ■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information. ■ Examines information/data for relevance and accuracy. ■ Analyzes data, integrates multiple items of data and contrasts conflicting data. ■ Presents complex ideas/information and poses critical questions. ■ Compares multiple viewpoints, relates intent of occupational/technical desired results and analyzes communication. ■ Demonstrates sensitivity to customer concerns/interests. ■ Understands continuous improvement process and suggests system improvements/modifications.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – C. Communicate with manufacturing and other departments regarding regulatory and compliance practices

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C8. Assist in training programs	<ul style="list-style-type: none"> ■ Training on regulatory compliance is provided to employees. ■ Training records are reviewed or audited to ensure training is up-to-date. ■ Deviations are reviewed to identify trends. 	<ul style="list-style-type: none"> ■ Summary of deviations and trends is complete, accurate, and submitted to appropriate party. ■ Knowledge of regulatory compliance. ■ Knowledge of training records and training requirements. ■ Knowledge of medical and industry terminology, jargon, and acronyms. ■ Knowledge of the data contained in the discrepancy reports. 	<ul style="list-style-type: none"> ■ Identifies training needs, conducts task-specific training, and coaches others to apply related concepts. ■ Compares multiple viewpoints and relates intent to desired results. ■ Uses previous training/experience to predict outcomes. ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Presents complex ideas/information and poses critical questions. ■ Demonstrates creative thinking process while problem solving. ■ Records information accurately, completes documentation, and summarizes information.
C9. Assist with resolution of quality issues	<ul style="list-style-type: none"> ■ Existing investigation records and reports are reviewed or investigation is initiated. ■ Investigation is performed and completed in accordance with company policies and procedures in a timely manner. ■ Investigation team members are communicated with effectively. ■ Proposed corrective action is reviewed to ensure compliance with regulatory requirements. 	<ul style="list-style-type: none"> ■ Ability to locate existing investigation records and reports. ■ Knowledge of company policies and procedures regarding investigations. ■ Knowledge of regulatory requirements. 	<ul style="list-style-type: none"> ■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information. ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Recognizes ethical issues and demonstrates trustworthiness. ■ Presents complex ideas/information and poses critical questions. ■ Performs given set of tasks and follows schedules.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – D. Participate in interactions with regulatory agencies

KEY ACTIVITY	PERFORMANCE INDICATORS <i>How do we know when the task is performed well?</i>	TECHNICAL KNOWLEDGE <i>Skills, abilities, tools</i>	EMPLOYABILITY SKILLS <i>SCANS skills and foundational abilities</i>
D1. Perform literature searches on regulatory requirements	<ul style="list-style-type: none"> ■ Search is pertinent to the assigned topic. ■ Search includes bibliography. ■ Search is complete and accurate in accordance with request. 	<ul style="list-style-type: none"> ■ Knowledge of the topic. ■ Knowledge of current literature sources. ■ Ability to utilize electronic search tools. 	<ul style="list-style-type: none"> ■ Selects/obtains data/information relevant to the task. ■ Records information accurately, completes documentation, and summarizes information. ■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details.
D2. Assist with submission, preparation, and with international documents and licenses	<ul style="list-style-type: none"> ■ Submission plan is generated and assignments and timelines are communicated to appropriate personnel. ■ Critical milestones are identified and tracked, reminders are sent to contributors, and timeline slippage is communicated to supervisor. ■ Submission is properly compiled, paginated, copied, and bound, with proper cross-references included. ■ Submission is in compliance with regulatory requirements and company policies and procedures. ■ Initial draft is issued for internal review, and comments are collated. ■ Where applicable, input from technical staff is formatted into appropriate draft. ■ Final draft of submission is proofed and all errors are corrected. ■ Submission is built on previous submissions and clearances. ■ Procedures for international documents and licenses are completely followed. 	<ul style="list-style-type: none"> ■ Knowledge of processes, timelines, and procedures for preparing submissions. ■ Knowledge of critical milestones for preparing submissions. ■ Ability to compile, paginate, copy, bind, and cross-reference submission. ■ Knowledge of regulatory requirements and company policies and procedures. ■ Knowledge of internal review procedures. ■ Knowledge of contents of submissions. ■ Knowledge of previous submissions and clearances. ■ Knowledge of procedures for international documents and licenses. 	<ul style="list-style-type: none"> ■ Prepares and organizes multiple schedules, manages timelines, and recommends timeline adjustments. ■ Examines information/data and recommends action plan. ■ Presents complex ideas/information and poses critical questions. ■ Records information accurately, summarizes/paraphrases information, and creates original documents. ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Uses previous training/experience to predict outcomes. ■ Performs assigned tasks, follows rules/policies/procedures and pays attention to details.
D3. Assist with regulatory document control	<ul style="list-style-type: none"> ■ Final version of submission is properly archived and distributed. ■ Supporting documentation is retained in accordance with company policies and procedures and regulatory agency requirements. ■ Receipt of submission is tracked as assigned. 	<ul style="list-style-type: none"> ■ Knowledge of archival and distribution procedures. ■ Knowledge of company policies and procedures and regulatory agency requirements. ■ Knowledge of receipt tracking procedures. 	<ul style="list-style-type: none"> ■ Performs assigned tasks, follows rules/policies/procedures, and pays attention to details. ■ Analyzes data, integrates multiple items of data, and contrasts conflicting data. ■ Analyzes organization of information and transfers information between formats.

CONCENTRATION: RESEARCH, DEVELOPMENT, AND MANUFACTURING

Critical Work Function – D. Participate in interactions with regulatory agencies

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<p>D4. Assist with preparation for FDA meetings</p>	<ul style="list-style-type: none"> ■ Plan to develop pre-meeting document is generated and assignments and timelines are communicated to appropriate personnel. ■ Critical milestones are identified and tracked, reminders are sent to contributors, and timeline slippage is communicated to supervisor. ■ Pre-meeting document is properly compiled, paginated, copied, and bound, with proper cross-references included. ■ Pre-meeting document is in compliance with company policies and procedures. ■ Initial draft is issued for internal review and comments are collated. ■ Where applicable, input from technical staff is formatted into appropriate draft. ■ Final draft of document is proofed and all errors are corrected. ■ All meeting logistics are set up as assigned. 	<ul style="list-style-type: none"> ■ Knowledge of processes, timelines and procedures for preparing document. ■ Knowledge of critical milestones for preparing document. ■ Ability to compile, paginate, copy, bind and cross-reference document. ■ Knowledge of regulatory requirements and company policies and procedures. ■ Knowledge of internal review procedures. ■ Knowledge of contents of document. 	<ul style="list-style-type: none"> ■ Examines information/data and recommends action plan. ■ Analyzes situation/information, considers risks/implications, and compiles multiple viewpoints. ■ Recognizes job tasks and distributes work assignments. ■ Encourages/supports team members. ■ Records information accurately, summarizes/paraphrases information and creates original documents. ■ Presents complex ideas/information and poses critical questions. ■ Pays attention to details.
<p>D5. Keep current on regulatory requirements</p>	<ul style="list-style-type: none"> ■ Sources for regulatory updates and proposals are thoroughly reviewed. ■ All relevant sources and media are searched. ■ Appropriate personnel are informed effectively and in a timely manner. 	<ul style="list-style-type: none"> ■ Knowledge of sources for regulatory updates and proposals. ■ Ability to locate sources. ■ Knowledge of the Web and electronic search techniques. 	<ul style="list-style-type: none"> ■ Probes to gain knowledge/information, qualifies/analyzes information, and interprets and summarizes information. ■ Understands computer operations, utilizes integrated/multiple software, locates and retrieves information/data and utilizes networks. ■ Presents basic ideas/information. ■ Performs given sets of tasks and follows schedules.
<p>D6. Assist with inspections and audits from regulatory agencies</p>	<ul style="list-style-type: none"> ■ Requested documentation is obtained and delivered to appropriate personnel. ■ All company policies are followed. ■ Confidentiality is maintained in accordance with company policy. ■ Upon request, notes are taken of the inspection. 	<ul style="list-style-type: none"> ■ Ability to obtain documentation. ■ Knowledge of company policies. ■ Knowledge of confidentiality policies. 	<ul style="list-style-type: none"> ■ Selects/obtains data/information relevant to the task. ■ Understands the organization and follows processes and procedures. ■ Recognizes ethical issues and demonstrates trustworthiness. ■ Records information accurately, completes documentation, and summarizes information