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David petok

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| profile | Passionate, collaborative, and diligent regulatory affairs professional with experience in Tech/Software, Medical Device, Pharma, Food, Supplements and Cosmetics. |
| Experience | February 2020 – Present **COMPLIANCE DOCUMENT SPECIALIST,** L7 INFORMATICS INC.   * Responsible for authoring and updating all product SDLC documents for each major, minor, patch and hotfix release (12+ documents)  Implemented/responsible for QMS for L7 Informatics including Deviation, CAPA, NCR, Change Control, employee training * Executed IQ/OQ/PQ qualification of new software tools used to create L7’s product * Assist in software verification and validation testing as applicable * Responsible for bug management/risk control for anomalies discovered in testing * Identified and implemented regulations, standards and guidance in the software development lifecycle for L7’s product from ISO 13485, ISO 14971, IEC 62304, CFR 211, CFR 820, CFR 11, GAMP 5, WHO, IMDRF, CAP/CLIA and ICH guidelines. * Performed internal audits and assisted in customer/external audits  Tools used: Atlassian (JIRA, Confluence, Bitbucket) SpiraTeam (test case management system) ZenQMS (electronic quality management system)  October 2017 – February 2020Regulatory Compliance Supervisor, Premier Research Labs  * Responsible for meeting current FDA dietary supplement label compliance (350+ labels) * Manage 4 direct reports * Internal audits and external supplier audits * Wrote Toxicological evaluations, Product Safety Evaluations, and White Paper Exemptions for foods, dietary supplements and cosmetics * **NPN procurement** for entry into Canadian market * **NOP’s USDA Organic** Certification on 4 products * **Non-GMO Project Verification** on 12 products * **OU Kosher Certification** on 130+ products * **Supplier Qualification Program** and FSVP/FSMA compliance * **Prop 65 Litigation** * **FDA’s Mandatory 2020 Labeling Update** (created calculator for this similar to LabelCalc/ESHA Genesis software) * Implemented Profit Sharing Program * Implemented cost savings measures totaling to $115,000 in 2019  August 2016 – October 2017Quality Control supervisor, premier research labs  * Developed a team of 6 employees to deliver laboratory results against a dynamic production schedule of food, dietary supplements and cosmetics (250+ products) * Lead OOS/OOT, NCMR, DEVIATION, CAPA, and Significant Quality Events (SQE) * Managed Expired Raw Material requalification program * Performed Quality Releases of all raw materials, components, in-process materials, and finished products * Point of contact for Laboratory Related OOS’s, Deviations, NCMR’s and CAPA’s  July 2015 – August 2016Quality Control Lab Technician, premier research labs  * Performed USP physical property/wet chemistry tests on raw materials to finished products * Ensured laboratory, production areas, and testing methods were cGMP and CFR 111 compliant, followed USP methods while maintaining GDP * Environmental micro, allergen, air, and water monitoring (via Hygiena and Neogen ATP/Allergen Swabs) and via incubation, plating, and a BioLumix System.  August 2014 – May 2015Chemist, Cudd Energy Services  * Performed rheological analysis of fracturing fluids in order to verify quantities to be used in field and determine improvements where necessary * Provided strict performance testing of numerous chemicals from vendors in order to lower costs and make big economic decisions for CES. * Created SOP’s, WI’s and notebooks for P.E.’s and lab personnel on CES fluids |
| Education | B.s. Biology, the university of texas at san antonio 2010 - 2014 Graduated with concentration in microbiology and immunology |