LaVonne Waldon
Client Services Manager
Office Manager

LaVonne Waldon is Client Services Manager at Paladin Medical,®Inc.

LaVonne's first responsibility is to ensure the clients have what they need to facilitate company services. She provides a wide range of skills to ensure smooth office management and communication with the clients. She facilitates communication between the President and other consulting staff concerning client requirements.

Ms. Waldon is responsible for accounts receivable and all client invoices. She is also the office specialist in various technical and accounting software databases. She manages the client document portal and interfaces with website and IT services to maintain office functions.

Ms. Waldon oversees production of the submission publication phase for FDA applications, converting and compiling the variety of document types to the format accepted by FDA. She ensures the applications are done and out the door on time.

LaVonne manages the office "library", which includes template procedures for quality systems and technical training articles on medical device issues ranging from biomaterials to software validation. The Paladin Medical, Inc. training and education database has proven time and time again to provide the information to clients as its needed in their corporate development.

To keep abreast of the everchanging medical device industry; Paladin Medical has invested in continued education for Ms. Waldon. The focus for 2018 is the impact of ISO 13485:2016 and how the standard may require changes to the medical device manufacturers' quality management systems (QMS).

The ISO 13485:2016 is a global standard for medical device quality management systems

(QMS), which replaces the previous version from 2003. The new revision places a greater emphasis on QMS throughout the supply chain and product lifecycle, as well as device usability and postmarket surveillance requirements. Beginning February 28, 2019, the guidance says, "any existing certification issued to ISO 13485:2003 will not be valid."

"Paladin Medical will continue to recommend that small startups initiate their quality systems based on 21 CFR 820, but now our templates can help integrate those requirements with the current version of ISO 13485:2016."

Recent classes attended:

ISO:13485:2016 Internal Quality Systems Auditor
Minneapolis, MN
3 day course BSI Group America
https://bsi.learncentral.com

The New ISO 13485:2016 and Comparison with 21 CFR 820 – how to comply with both in the same organization
Minneapolis, MN
1 day course Compliance for All
https://compliance4all.com

Excel Spreadsheet Validation for FDA 21 CFR Part 11
Minneapolis, MN
1 day course Compliance for All
https://compliance4all.com