# ANDRE D. BUTLER

direct: 954.501.8099

Pembroke Pines, FL 33084

email: andre.butler@adbccro.com


## SENIOR CLINICAL PROJECT MANAGER

***Accomplished Sr. Certified Clinical Research Project Manager with extensive hands-on experience providing Clinical, Data Management and Biostatistics Support***

Goal driven, outcome focused, and highly motivated professional with extensive experience in fast paced biotechnology settings, offering solid project management of clinical operations to include end to end management from for 3 main critical areas of clinical operations.

***Clinical:*** *Protocol Development, Investigator/Site Enrolment, Data Monitoring, Adverse Event Management, Site/Data Audits, and Site Close-Outs*

***Data Management:*** *CRF Design, Database Development, Risk Based Monitoring, Medical Data Coding, system Validation*

***Biostatistics:*** *Study Design, Data Analysis Plans, Statistical Data programming, Data Reporting*

***Clinical Study Compliance****: ICH E6 (Good Clinical Practice GCP), 21 CFR Part 11, AAMI, Applicable laws for device and Drug Accountability, 45 CFR Part 164 - HIPPA Regulation Adaptations and implementations*

Experience includes ensuring that operating procedures and quality records are in compliance with quality standards and applicable regulatory requirements. Adept at providing oversight to clinical quality and validate medical device and related software systems. Technically proficient in a wide variety of firmware, enterprise, desktop, mobile applications and industry relevant software.

Results oriented leader with a solid reputation for meeting deadlines and demonstrated skills in building effective teams, driving facility improvements as well as identifying strategic business solutions. Succinct communicator (both written and verbal), with a demonstrated ability to work well in a team environment; possessing a high energy level, keen attention to detail, and a commitment to the continuous improvement process. Capable of multitasking within fiercely competitive and fast-paced environment, without compromising the quality of projects.

## EDUCATION

**CERTIFIED CLINICAL RESEARCH PROFESSIONAL, CCRP**

*Society for Clinical Research Association (SoCRA)*

**BACHELOR OF COMPUTER SCIENCE/BACHELOR OF SCIENCE IN MICROBIOLOGY**

*Florida Atlantic University, Davie, FL, 2000*

**ASSOCIATE OF ARTS IN PRE-MEDICINE WITH HONORS**

*Broward Community College, Margate, FL, 1998*

## MOST RELEVANT WORK EXPERIENCE

*Utilize full understanding and knowledge of domestic and international GCP regulations and industry standards for the development, validation and execution of Clinical Research. Adept at providing quality review of documentation, project management and coordination of staff and contractors by providing consistent, complete, and timely communication throughout all phases of projects. Possess a demonstrated capability to quickly gain a detailed understanding of a process to optimize efficiencies and improve quality.*

**ADB CONSULTING AND CRO INC., Hollywood, FL** *January 2004 to Present*

**Sr. Certified Clinical Research Project Manager:** ***Provided Clinical Research Consulting for Medical Device and Pharmaceutical companies***

***Clinical***

Executed Gap analysis reviews to determine clinical process deficiencies and readiness as it pertains to ICH E6 (GCP) for study closures, bio-monitoring readiness and site close outs.

Established clinical operating procedures to include but not be limited to clinical study management procedures, clinical site monitoring, clinical data management plans, and clinical systems master validation plans

Managed Clinical Site operations to include enrolment standard operating processes (SOPs) for patient enrolments, clinical site enrolments, and investigator enrolments, clinical coordinator qualifications, IRB Correspondences, HIPPA Regulations adaptations, clinical data monitoring to ensure that Case Report Forms (CRFs) match medical records.

***Data Management***

Executed Gap analysis reviews to determine data management process deficiencies and readiness as it pertains to data management plans, data management operations, data validation plans (discrepancies/query management) and medical coding plans.

Developed paper based Case Report Forms (CRFs) as multiple parts to collect study data.

Developed Fax Based Electronic Systems, Electronic Data Capture (EDC), Remote data Capture (RDC) to collected Clinical Data

Executed Medical Data Coding and auto-encoding to include Adverse Event and Concomitant Medications using systems such as MEDDRA, WHODRUG, ICD9 etc.

Validated Clinical systems to ensure compliance with 21 CFR Part 11. Validation included on-premises and Software as a Service (SaaS) Systems

Defined clinical data validation checks to execute automated programming to generate Clinical Data Discrepancies and Data Clarification forms (DCFs). Query management

***Biostatistics***.

Executed Gap analysis reviews to determine biostatistics process deficiencies and readiness as it pertains to data analysis plans, data programming operations, and TLG transcriptions.

Developed Clinical Data Analysis Clinical protocol Stipulations in accordance with Biostatisticians

Developed Data Analysis Plans based on the Clinical Protocol

Developed and validated Data Programming Scripts and Programs

Developed TLG for Clinical Reports

Prepared FDA Submission packages to support Pre-Market Approval (PMA), 510k Clearances and other FDA and European Submissions.

**Medical Device Consultant (Product Development and Quality Assurance)*: Provided high level medical device consulting for Product Development and Quality Assurance.***

Provided Medical Device product consulting for New Product Development, Product Enhancements, product prototyping, and Feasibility Assessment.

Provided Medical Device Planning and commercialization timeline planning and implementation to involve cross departmental function operational requirements. Departmental planning included: Advance product Development, Product Development, Quality, Clinical, and Manufacturing.

Provided submission requirement assessments for US (510K) and CE mark product introductions, Assessments included ISO 13485 Certifications and Technical File generation and submissions for medical CE mark. In addition, assessed submission requirements to include predicate analysis for 510K submissions.

Provided consultation for implementation of Quality Systems to satisfy 21 CFR Part 820 and ISO 13485 include all areas of the regulations.

Provided technical consultation for user need implementation in consumer and profession user based products. Methods of implementation, platforms selection, technology selection, user interaction strategies are among some of the technical

**New Product Development Project Manager*: Managed various new product development, continued development or redevelopment projects for medical devices and software products***

Executed product development plans (PDPs) to define product development from concept through design, prototyping, pre-production and eventual production for product (mechanical and or electrical) and software

Executed prototype and feasibility development planning of products and software

Managed various disciplines to include electrical, mechanical, software engineers utilizing various solutions for design to include but not be limited to Photoshop, SolidWorks, Visio, Inventor, and OrCAD

Employed various Integrated Development Application for development to include Visual Basic, JAVA, Visual C++, C, C#, .NET, and SQL to drive various product development.

Incorporated Compliance Regulation in Product Development to include but not limited to:

- FDA QSR 21 CFR Part 820, Quality System Regulation
- Medical Device Directives: MDD 93/42/EEC
- Canadian Medical Device Regulations: CMDR SOR/98-282
- ISO 10993-1 "Biological evaluation of medical devices
- ISO 14971:2012, Medical Devices---Application of risk management to medical device
- ISO 15223 – 1 Medical Devices – Symbols to be used with medical devices,
- ANSI/AAMI ES60601-1 Medical electrical equipment–
- IEC 60601-1-2 Medical electrical equipment
- IEC 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices
- IPC-A-610E Acceptability of Electronic Assemblies
- ISTA 3A Series General Simulation Performance Test Procedure1
- ASTM D4169-09, Standard practice for performance testing of shipping containers and systems
- IEC 62304 Medical Device Software – Software Life Cycle Processes
- AAMI TIR49:2013, Design of training and instructional material for medical devices used in non-clinical environments.

**Validation Project Manager:** ***Custom Software, Enterprise Software, Software as a Service (SaaS), Commercial Off the Shelf (COT) Software, Mobile Device Applications, and Medical Device Software Validation***. Provide software validation and integration services to support Medical CE and US regulations to support compliance of product, processes, software, and equipment validation. Support various projects to maintain compliance with but not limited to cGMP (21 CFR Part 820), ISO 13485, 21 CFR part 11, IEC62304, AAMI TIR36, and ISO14971. Experienced in preparation and review of Design Input, Design Output, Verification and Validation Protocols to include but not limited to Standard Operating Procedures (SOP), Software Requirement Specifications (SRS), Functional Specifications (FS), Traceability Matrices, Design Input Requirements (DIR), Software Validation Protocol (SVP), and Installation, Qualification (IQ), Operations Qualification (OQ), Performance Qualification (PQ), Risk Management (RA), Risk Assessments (RA/RAR), and Failure Mode and Effects Analysis (dFMEA, pFMEA, sFMEA, cFMEA)

**Quality Systems Project Manager:** ***Managed the development, implementation and validation of Quality Management Systems***

Managed the custom development of Quality Management Systems to handle documents, records and electronic signatures.

Managed the selection, configuration, installation, integration, implementation and validation of custom and commercial off the shelf (COTS) enterprise quality management systems.

Implemented both On-Premises and Software as a Service (SaaS) configurations in multi user environments capable of supporting 500+ users.

Managed the development of a wide variety of quality system processes and complementary electronic systems to include but limited to Document Management Systems, Return Management Systems, Corrective Action and Preventive Action (CAPA) System, Complaint Management System, Equipment Management Systems, Calibration Management Systems, Product and Component Management Systems

Systems managed included but was not limited to: Expandable ERP System, Agile Product Lifecycle Management (PLM) System, Agile Quality Management (AQM) Systems, QAD ERP MRP Systems, Grand Avenue Document Management System, Preventive Maintenance System, BigFoot Software, GageTrak Calibration Management Systems, TMS Training Management Systems, Etc.

Utilized System Development Life Cycle (SDLC) methodology in validations

Established compliance to clients standard operating procedures, ISO 13485, ISO 14971, 21 CFR Part 820, 21 CFR Part 11, AAMI TIR36

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## EARLY CAREER

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| | **PROGRAMMING ADMINISTRATOR, Purdue Pharma L.P., Stamford, CT** | **2003 to 2004** |
| | **CLINICAL MANAGER, Medtronic, Santa Rosa, CA** | **2002 to 2003** |
| | **CLINICAL SYSTEMS MANAGER, Medtronic Ave, Sunrise, FL** | **1999 to 2002** |
| | **DATABASE ADMINISTRATOR, World Medical, Plantation, FL** | **1998 to 1999** |
| | **SYSTEMS ANALYST, The Answer Group, Margate, FL** | **1996 to 1998** |

## PRESENTATIONS

***Exhibits and Presentation of Validation Services, Medical Device Manufacturing (MDM)***

***Exhibits and Presentation of Validation Services, Florida Medical Device Symposium (FDMC)***

***Exhibits and Presentation of Validation Services, Generic Pharmaceutical Association (GPhA)***

***Seminar on the effects of the phytoestrogen, Genistein, on proliferating cancer cells***

## PUBLICATIONS

*Cytotoxic potential of the phytochemical Genistein Isofavone (4', 5' ,7-Trihydroxyisoflavone) and certain environmental chemical compounds on testicular cells. Biology of Cell 1999 - 2000*

Caspase-3 protease activation during the process of Genistein-induced apoptosis in TM4 testicular cells. *Biology of Cell 1999 – 2000*

*Potential Effects of Combined Genistein Isoflavone and the Glucocorticoid Dexamethasone on Testicular Cells. James Kumi-Diaka, Andre Butler and Vu Nguyen. Journal of Nutrition March 1, 2000*

*Talent LPS AAA stent graft: Results of a pivotal clinical trial, 2002 Investigators - Frank J. Criado, MD, Ronald M. Fairman, MD, Gary J. Becker, MD Contributors: Simon Fuger, Jeff Elkins, Deepak Srikant, Carol Barbre, and Andre Butler - Journal of Vascular Surgery March 1, 2000*

## TECHNOLOGICAL SKILLS

Strong knowledge to include but not limited to:

**ERP/MRP**: QAD Enterprise Software, Expandable, Dynamics AX, 32Soft, NetSuite etc.

**Clinical Trial Management Systems (CTMS)**: Medrio, TrialMaster, Custom Systems

**Clinical Data Management Systems (CDMS)**: DataFax, Oracle Clinical, OpenClinica, MetaData, Medrio, TrialMaster, etc.

**Statistical Packages**: SAS, MiniTab

**Data Programing Packages**: SAS, R, SSIS

**Quality Management System**: Agile Product Lifecycle Management, Documentum, Grand Ave, SharePoint,

**Manufacturing Support:** GageTrak, Preventative Maintenance, BigFoot, Maintenance Connection

**Integrated Development Environments:** LabView, LabWindows, Visual Studio (.Net, C#, Visual Basic), Visual Basics for Applications, Eclipse (JAVA, JAVA Script), xCode (iOS), SAS

**Desktop Publishing:** Adobe Photoshop, Adobe Illustrator, Solidworks, AutoCAD, MS Word, MS Excel, MS Access, MS Project

**Integrated Development Environments:** LabView, LabWindows

**Operating Systems:** Windows Desktop (, Windows Server (2003, 2008/2012/2016)

**Virtual Hardware:** Hypervisor, VMWare, VirtualBox

**Cloud Services:** Amazon Web Services, GoDaddy, DropBox iCloud

**Version Control:** Team Foundation Server, CVS, GitHub, JIRA, Confluence

**Hardware:** National Instrument PXI, DAQ, Cisco Systems

## REFERENCES

***Available upon request***