Corporate Capabilities:

- Program Management
- Financial Management and Systems Support
- Information Technology Solutions and Support
- Knowledge Management and Communications

Supporting the Mission of Public Health at the U.S. Department of Health and Human Services

Macfadden has provided exceptional program management and information technology solutions at HHS for over 20 years. Our work supports HHS's mission to advance public health, turning data into knowledge that improves operational performance and enhances critical decisions. We bring in-depth familiarity with HHS enterprise architecture and environments from both a technical and a business process perspective ensuring that systems and solutions meet the real, day-to-day needs of scientists and regulators.

Systems Operations and Maintenance (O&M); and Development, Modernization and Enhancement (DME)

Macfadden's corporate experience at HHS includes developing, maintaining, upgrading and integrating critical IT systems. In particular, we have extensive domain knowledge of FDA's Enterprise-wide and individual Center-based IT systems. Mission-critical systems that we have supported include:

- **FDA CDER Automated Drug Information Management System (ADIMS)** Macfadden develops, operates, maintains, modifies, and enhances ADIMS, an integrated electronic information management system. In addition to overall quality assurance, our work at ADIMS includes ongoing support for the LX Refresh systems and the Automated Submission Receipt (ASR) system; as well as participation in integrated project teams and change control board activities. We support the integration of over fifty systems into ADIMS, including the CDER Oracle Management Information System (COMIS) and the Division File System (DFS)
- **FDA Substance Registration and Ingredient Dictionary (SRS/ID)** Macfadden provides life cycle operations and maintenance support including gathering user requirements, prototyping, design, coding, testing on development and test servers, participating in user acceptance testing, and supporting the deployment to production
- **FDA CFSAN Mission Accomplishment and Regulatory Compliance Services – Compliance Management System (MARCS-CMS)** Macfadden was responsible for the design, development and ongoing maintenance of the MARCS-CMS. We integrated MARCS-CMS with legacy systems and worked with stakeholders to define system requirements, technical design and user interface. We also conducted rapid application systems development and created a new web interface that increased end-user system usage

Macfadden and members of the MARCS CMS team received the 2008 FDA Honor Award in the category of Cross-Cutting Group Recognition Awards.

- **FDA CFSAN Automated Research Tracking System (CARTS)** For this inter-center system, designed to track all CFSAN research projects, Macfadden designed and developed the initial releases and provided DME support and full lifecycle configuration management, as well as requirements, design, testing and migration support
- **FDA CFSAN Scientific Computing** Macfadden provided O&M and DME support for IT systems and services supporting FDA CFSAN business functions, including IT application systems and scientific computing resources

HHS Experience and Relevant Capabilities

- Configuration Management
- Data Management
- Enterprise Integration Services
- Enterprise Search Solutions
- Full Life Cycle Software Application O&M and DME
- Functional System Support
- Information Assurance (FISMA Compliance/ISSO Support)
- Oracle Business Intelligence, Federal Financials and RDMS Expertise and Support
- Program and Project Management
- Quality Assurance/Quality Control
- Software Training and Helpdesk Support
- Systems Analysis, Engineering, Integration and Testing
- System Architecture Design

Relevant Contract Vehicles

FDA Enterprise System Life Cycle Management Support (ELMS) Tier 2 (Small Business Prime)

GSA Schedule 70 Information Technology

GSA Schedule 520 Financial and Business Solutions (FABS)

GSA Schedule 874 Mission Oriented Business Integrated Services (MOBIS)

NIH Chief Information Officer – Solutions and Partners III (CIO-SP3) (Subcontractor)

FDA Information Technology for the 21st Century (ICT 21) (Subcontractor)

FDA Regulatory Review Support IDIQ (Subcontractor)

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Functional Support for Financial Systems

Macfadden provides strategic functional support for HHS systems, including the Unified Financial Management System (UFMS) and the Financial Business Intelligence System (FBIS). We provide expertise in Oracle Federal Financials Project Management, OBIEE Implementation and Support, and Audit Compliance and Policy Development.

Macfadden provides expert guidance to support the ongoing migration of UFMS from Oracle 11g to R12. We work with all HHS operating divisions to define business needs, identify issues and determine how the new version can solve existing issues.

- Program management support for development and operation of UFMS and FBIS
- Participate in requirements, evaluation team and change control board meetings
- Perform R12 functional and technical overviews and develop design specifications
- Provide systems development support including developing functional business intelligence/dashboard reporting requirements, helping establish enterprise architecture, defining user requirements, & participating in User Acceptance Testing
- Provide O&M support including tracking and evaluating user enhancement requests, assisting in prioritization of issues, monitoring daily system performance, and helping to oversee system upgrades and development of technical solutions
- Support A-123, FFMIA and FISMA audits, including performing compliance reviews, developing guidance and training programs for HHS operating divisions to improve compliance with requirements, and participating in audit walkthroughs
- Develop, implement and monitor a Policy Compliance Program to resolve audit findings

Information Assurance / Information Technology (IT) Security

Macfadden developed and implemented IT security policies and procedures to ensure compliance with Office of Management and Budget, National Institute for Standards and Technology, and Federal Information Security Management Act (FISMA) guidelines. We established security management policies and procedures, developed contingency and operations plans, and obtained Certifications and Accreditations.

At FDA CFSAN, Macfadden developed automated methods of tracking task assignments and status to ensure CFSAN's systems met security requirements. Our application of automation reduced the production time of security-related self-assessment documentation.

- Provided Information Systems Security Officer (ISSO) support to ensure IT systems at FDA were operated, used, maintained and disposed of in accordance with internal security policies and procedures
- Prepared information security improvement plans for major systems and addressed security concerns
- Managed a large-scale project to bring IT systems and applications into compliance with a basic security framework and establish a compliant, well-managed security program
- Developed risk analyses and contingency plans and performed FISMA evaluations

Enterprise Search Technologies

Macfadden developed, implemented and provided O&M support for the FDA Enterprise Search (ES) platform, integrating search technologies and strategies into the FDA's IT applications and centralized enterprise search user interface. This resulted in improved, more efficient access to data critical to FDA business processes for over 10,000 FDA staff across the entire agency. Macfadden's expertise and support enabled the ES platform to evolve to a mission-critical system supporting nearly all FDA Centers and offices.

Macfadden reduced search times from as long as 30 minutes to less than one second by taking disparate collections of information and making them easily searchable by users across the agency.

- Collaborated with all FDA Centers and Offices to integrate ES into FDA repositories
- Migrated the ES system from a stand-alone Windows server environment to a consolidated virtual machine (VM) environment
- Worked with the Center for Tobacco Products (CTP) to index over a terabyte of regulatory data
- Provided CTP with a solution to more easily access millions of documents and terabytes of data. Successfully reduced the time for metadata capture of tobacco industry documents from as long as three months to one week

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