



FDA

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FDA Responsibilities

FDA is responsible for...

- protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation
- regulating tobacco products
- advancing the public health by helping to speed product innovations
- helping the public get the accurate, science-based information they need to use medicines and foods to improve their health
- FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.



FDA Regulated Products

■ Products regulated by FDA include:

- All foods except non-game meat and poultry
 - Human food, Animal feed and Pet food
- Cosmetics
- Dietary Supplements
- All legal drugs (prescription and non-prescription, animal and human)
- Biological products including blood products, human vaccines, and tissues for transplantation
- Medical devices and products that emit radiation
- Tobacco products

■ Combined, these products represent about 1 Trillion dollars/year or 25% of consumer spending. This includes \$466 billion in food sales, \$275 billion in drugs, \$60 billion in cosmetics and \$18 billion in vitamin supplements.

■ FDA's budget is approximately \$1.6 billion a year -about \$4/year per taxpayer





Background

Infrastructure / IT Environment in 2007–2008: a “Perfect Storm”



- Significant weakness identified by external organizations — **reducing** Agency’s credibility
- External business driver — **changing** FDA’s business model
- Data centers’ (infrastructure) reliability and availability — **impacting** Agency’s Mission
- Security posture — **exposing** FDA’s systems and data
- Lack of systems documentation, standards, and structured development methodology — **limiting** enterprise architecture and standardization initiatives

Pressure to vacate Parklawn data center by 6/2010 —
Must vacate Parklawn by 8/2010



Background

Science Board, PDUFA, and GAO Findings



- **IT infrastructure is obsolete and unstable**
 - 80 percent of services are greater than 5 years old
 - Lack of significant controls to provide COOP and disaster recovery
- **Critical network components are not centralized to provide necessary security, redundancy, and continuity of operations**
- **Advances in science and technology have been outpacing the capabilities of FDA's IT infrastructure and systems**
- **Lack of data quality and ease of availability throughout the Agency**
- **Inability to use technology to improve regulatory effectiveness**



Background

External Business Drivers Impacting FDA



- **Globalization of the industries that the FDA regulates**
 - Growth in international footprint
 - Requires 24x7 information availability
- **Substantial growth in volume and complexity of information received by FDA**
 - Food recalls requiring fast, real-time collaboration with Industry
 - **Double** the number of adverse event reports and generic drug applications
 - **2.5x** increase in imports
 - Added significant number of new employees

Growth and complexity of FDA's Mission support is overburdening the Agency's existing infrastructure



Background

Systems Development Lacks Core Fundamentals



- **Standards for applications development not well documented or adhered to**
- **Limited documentation of “as-is” systems — knowledge resident with employees and/or contractors**
- **Employees with system knowledge leaving FDA or returning to Centers**
- **Development methodology (EPLC), including governance, not standardized or integrated, resulting in multiple Center-based methodologies**
- **Limited development and testing capabilities**



Overview

ICT21 Data Center Program Objectives



- Provide an Agency-wide, 21st-century computing infrastructure that is secure, scalable, flexible, and reliable to meet FDA's business missions
- Key attributes:
 - Tier 4-level **production** data center environment with a secure FDA computing environment
 - Formalized development, test, pre-production/UAT, and production environments
 - Utility-based infrastructure service including future cloud computing
 - Consistency and standardization through new, standard operational procedures and processes

The ICT21 Program is improving service, response times,
and overall performance



Data Center Engineering

Data Center Architecture



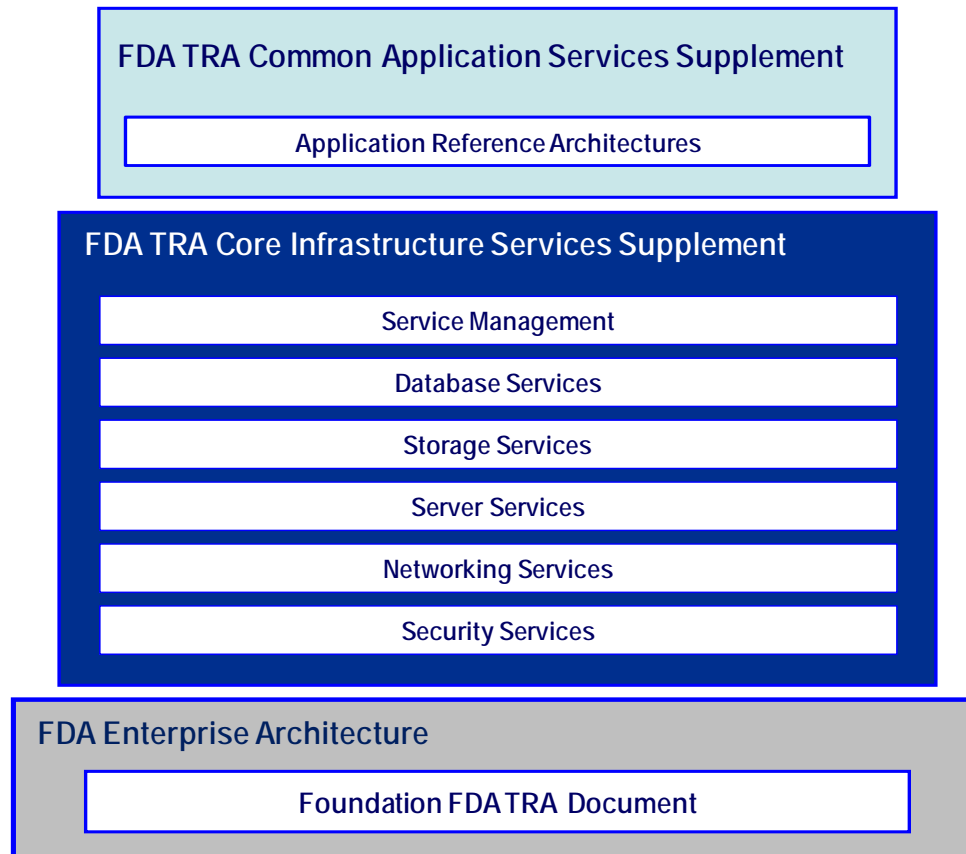
- **Formalize Life Cycle Environment**
 - Development and Test Environments in WODC
 - Pre-Production/UAT and Production Environments in CHDC
- **Multi-tier enclaves to secure applications and data**
 - Separate Web / Presentation Zone
 - Separate Application Zone
 - Separate Data Zone
 - Separate Intranet and Extranet enclaves
 - Management Zone for systems and security management
- **Utility-based infrastructure servers**
 - Shared storage using Storage Area Networks (SAN)
 - Server virtualization technology using VMware and Solaris LDOMs
- **Common Application and Database Services**

Achieved 89% virtualization



Data Center Engineering

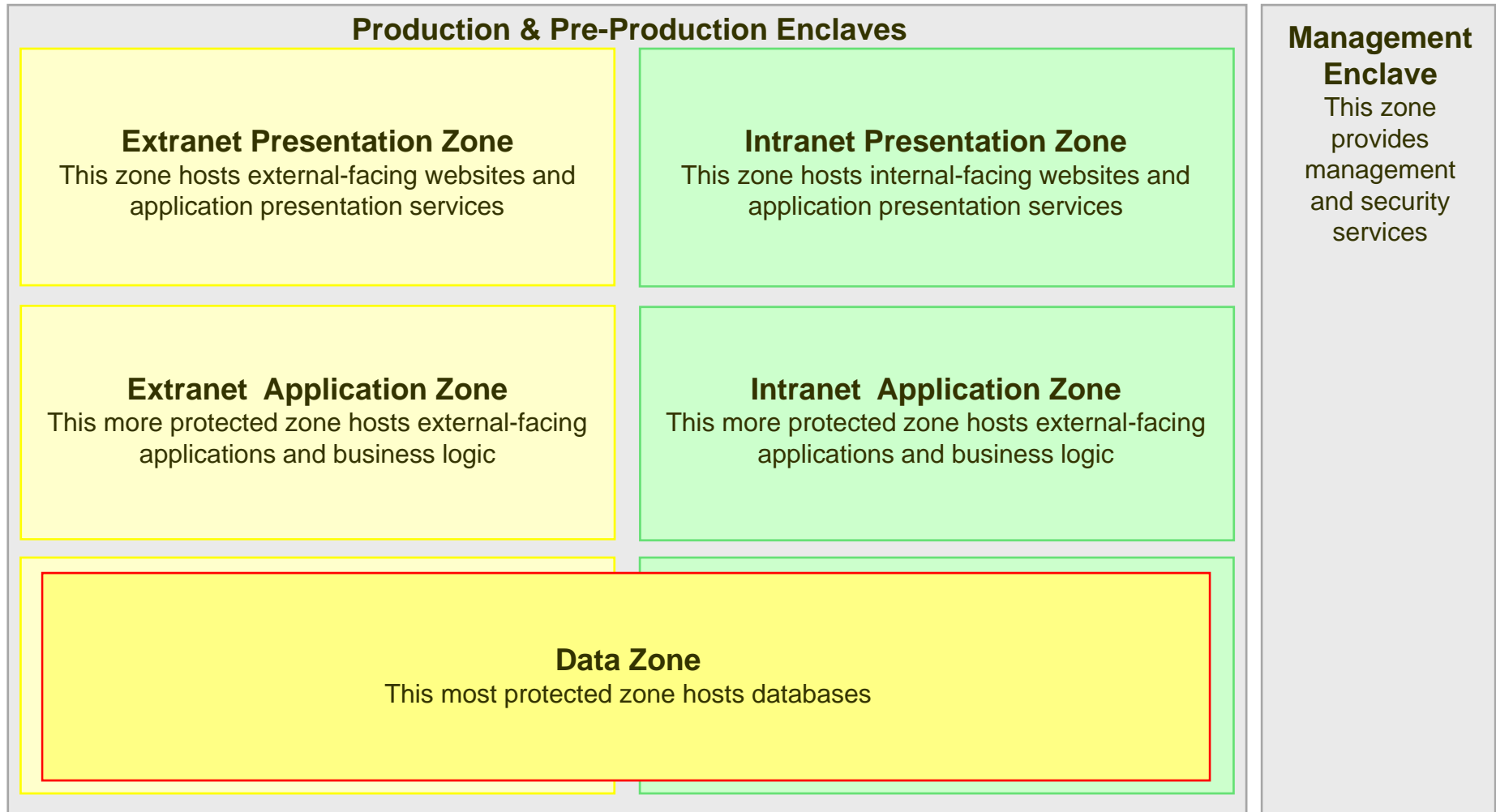
Created Framework for Infrastructure and Application Standardization





FDA's New Data Centers: Core IT Infrastructure

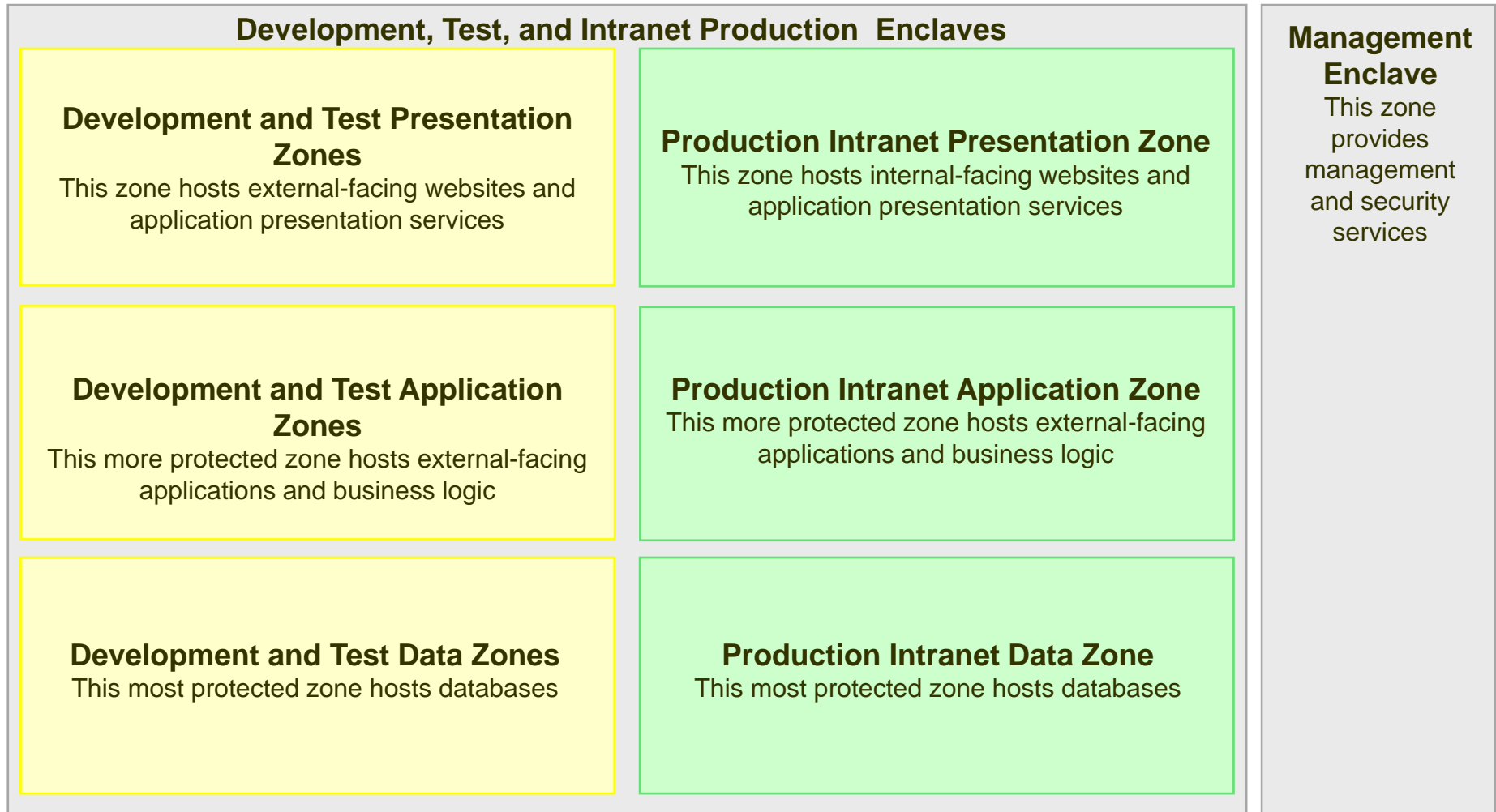
Data Center Architecture: Ashburn





FDA's New Data Centers: Core IT Infrastructure

Data Center Architecture: White Oak



Cloud/Virtualization Costs Comparison

