FDA Office of Acquisitions and Grants Services Overview

Presentation to the Association of Food and Drug Officials (AFDO)

February 3, 2016
• Who We Are/What We Do
• Contract vs. Grant
• Grant ‘Flexibilities’ vs ‘Limited’ Flexibilities of Contract T&C
• FDA State Contract and Grant Programs
OAGS Mission, Vision & Goals

Mission

Our mission is to provide high quality support to FDA programs by managing all contracts, and assistance agreements in a timely manner and at a reasonable cost.

Goals

- Stewardship and Customer Service
- Value and Cost Savings
- Performance and Professionalism

Vision

Our goal is to be an acquisition center of excellence by fostering strategic collaboration with our partners and empowering our workforce to achieve results that protect and promote the health of all Americans while maintaining the public trust.

• Enhance Center / OAGS Strategic Partnership in the Procurement Process
• Increase Efficiency, Transparency, and Accountability
• Achieve FDA and HHS Contracting Goals
• Achieve Administration Acquisition Reform Goals
• Ensure Compliance with Applicable Laws and Regulations (FAR, HHSAR)
What We Do

Grants and Assistance Agreements Branch

Negotiate, award and monitor federal funds awarded through various grant mechanisms. Award and administer Inter-Agency Agreements (IAGs).

State Contracts Branch

Contracts to support the Mammography Standards Quality Act, Food, Tissue and Feed Programs. These contracts commission the states to conduct inspections to ensure the quality and safety of the nations’ food, animal feed and medical devices.

Facilities Support Branch

Provides facility support, furniture, construction and renovation, architect/engineering services contracts and simplified acquisitions for all headquarters locations, Irvine, San Juan, and Dauphin Island.

Field Operations Branch

Provides support for National Center for Toxicological Research (NCTR) (Jefferson, AR) related work as well as lab supplies and lab equipment as designated.

Business Management Team (BMT)

Facilitates collaboration between OAGS and the FDA Center/Offices to provide early acquisition support and multidisciplinary technical expertise in order to make the acquisition.

Information Technology Branches (IT Acquisitions & Systems Technology)

All information technology related contracts and simplified acquisitions.

Services Branch

Service contracts and simplified acquisitions, including but not limited to, document control/records management, events management, management support services, guard services, moving, library support, custodial, etc.

Contract Operations Branch

Service contracts and simplified acquisitions, including but not limited to, studies chemicals/drugs/reagents, animals, lab equipment, etc.

Scientific Support Branch

Mission specific contracts and simplified acquisitions, including research and development requirements and lab supply and equipment requirements.

Office of Operations
Committed to Service. Dedicated to Progress
The Acquisition/Grant Enterprise

- **Acquisition/Grant system** – the integration of the process, policies, stakeholders, and management structure for executing the acquisition and grant functions.

- **Acquisition/Grant process** – the way in which an organization’s requirements are developed, prioritized, validated, planned, budgeted, and fulfilled. It covers the entire life cycle.

- **Stakeholders** – the team of enablers, customers, and partners involved in executing the acquisition and grant functions.

**Key Stakeholders**

- Budget
- Information Technology
- Requiring Organization
- Small Business
- Acquisition/Grants
- Legal
- Project Management
- Vendor Partners
- End User
- Accounts Payable

**Planning**

**Executing**

**Managing**
FY15 Snapshot

- Awarded 6,906 contract actions for a total of $1.55B

- Competition data:
  - Actions: 91% Completed
  - Dollars: 95% Completed

- Awarded 575 grants valued at $161M
Contracts vs. Grants
Federal Grant and Cooperative Agreement Act of 1977 (Public law 95-224)

Congress passed Act to:

(1) prevent misuse of grants
(2) provide guidance on proper use of acquisition vs. grants
Contracts vs. Grants

Act emphasizes choice of award instrument based on the purpose of the relationship, characteristics, and conditions

**Contract**: Used when purpose of transaction is to acquire property or services for *direct benefit of the federal government.*

**Grants/Cooperative Agreement**:  
• Principle purpose is to transfer money, property, or services to a recipient to accomplish public purpose of support or stimulation authorized by law [beneficiary is the ‘*public.*’]
Contracts vs. Grants

Contracts have significant less flexibilities than Grants

Let’s Explore.....
<table>
<thead>
<tr>
<th>Flexibility</th>
<th>GRANT</th>
<th>CONTRACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>A flexible instrument designed to provide money to support a public purpose. Assistance with few restrictions.</td>
<td>Very Limited Flexibility (varies by contract type): A binding agreement between a buyer and a seller to provide goods or services in return for consideration. May be unilaterally awarded at proposal stage without ability to negotiate terms and conditions</td>
</tr>
<tr>
<td>Statement/Scope of Work</td>
<td>Flexibility to change Scope of Work, Budget, Etc.</td>
<td>Develop by Government during acquisition planning process. Subject to amendment by Contracting Officer during solicitation process. Relatively inflexible as to scope of work, budget, and other changes. Once contract awarded, generally not permitted to change.</td>
</tr>
<tr>
<td>Results</td>
<td>Failure to perform less likely to result in legal action or financial consequences</td>
<td>Failure to perform can result in potential legal action or financial consequences</td>
</tr>
<tr>
<td>FLEXIBILITY</td>
<td>GRANT</td>
<td>CONTRACT</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>Terms and Conditions</td>
<td>Flexible Terms &amp; Conditions</td>
<td>Restrictive Terms &amp; Conditions</td>
</tr>
<tr>
<td>Competition in Contracting Act (CICA)</td>
<td>NO to CICA; YES to other agency competition requirements</td>
<td>YES to statutory requirement</td>
</tr>
<tr>
<td>Protests</td>
<td>NO – GAO protest jurisdiction does not extend to grants</td>
<td>YES</td>
</tr>
</tbody>
</table>
STATE CONTRACT PROGRAM
The Office of Partnerships (OP) manages various sole source and fixed price contract programs with States.

The purpose and focus of the programs are to:

- Leverage State regulatory resources
- Enhance coverage of FDA regulated establishments
- Cultivate positive working relationships
ORA State Inspection Programs

**Devices**

**Authority:** 21 CFR, part 803, Medical Device Reporting Regulation  
**Purpose:** Designed to obtain State assistance in the inspection Class I and Class II medical devices manufactures to determine compliance with the QSIT/GMP regulations.

**Egg**

**Authority:** 21 CFR 118: Production, Storage and Transportation of Shell Eggs  
**Purpose:** Acquire State assistance for the inspectional coverage of egg producing facilities covered by FDA’s final SE egg rule, specifically to:

- Conduct inspections of egg layer farms to assess compliance with 21 CFR 118: Production, Storage and Transportation of Shell Eggs, the “Egg Rule’
- Inspect person involved in holding or transporting eggs for shell egg processing or egg product facilities in order to verify compliance with refrigeration requirement during storage and transport
Feed

**Authority:** Federal Food, Drug, and Cosmetic Act (FD&C Act)

**Purpose:** Inspection and re-inspection of both licensed and non-licensed feed establishments to determine whether these firms manufacturing medicated feeds are compliance with key good manufacturing practices/regulations.

Food

**Authority:** Federal Food, Drug, and Cosmetic Act (FD&C Act)

**Purpose:** Inspection of commercial organizations with an emphasis on determining significant violations to the Good Food Manufacturing Practices (GMP), unsanitary conditions, and practices that may render the food adulterated or injurious to health.
ORA STATE PROGRAM – Con’t.

MQSA

**Authority:** Mammography Quality Standards Act (MQSA) of 1992

**Purpose:** Obtain State and local assistance in the inspection of certified non-Federal mammography facilities to document compliance with the mammography quality standards issued under 21 CFR Part 900.

Tissue

**Authority:** Federal Food, Drug, and Cosmetic Act (FD&C Act)

**Purpose:** Objective to minimize consumers’ exposure to food adulterated with illegal drug residues and eliminate the illegal use of drugs in food producing animals. Investigations are conducted to determine and document the cause of illegal drug residues and shipment of adulterated food drugs.
## ORA Inspection Programs

<table>
<thead>
<tr>
<th>Product</th>
<th>Contracts</th>
<th>Estimated Total Value</th>
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</thead>
<tbody>
<tr>
<td>FOOD</td>
<td>46</td>
<td>$11.5M</td>
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<tr>
<td>FEED</td>
<td>34</td>
<td>$2.9M</td>
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<tr>
<td>MQSA</td>
<td>44</td>
<td>$9.5M</td>
</tr>
<tr>
<td>TISSUE</td>
<td>6</td>
<td>$430K</td>
</tr>
<tr>
<td>EGG</td>
<td>8</td>
<td>$280K</td>
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<tr>
<td>DEVICE</td>
<td>2</td>
<td>$287K</td>
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What Is the Federal Acquisition Regulation?

• Codified at Title 48 of the Code of Federal Regulations (CFR)
• A system of uniform policies and procedures governing acquisitions by all federal executive agencies
• FAR Part 52 contains solicitation provisions and contract clauses

What Transactions Fall Outside the FAR’s Coverage?

• Notable examples are any agency contract or agreement that is not a procurement contract (i.e., not a contract that uses appropriated funds to acquire property or services for the direct use of the United States),
• Grants/cooperative agreements
• Transactions where Congress has authorized a government entity to acquire goods or services “notwithstanding
Guiding Principles for the Federal Acquisition System [48 C.F.R. §1.102(a)]

“is to deliver on a timely basis the best value product or service to the customer, while maintaining the public’s trust and fulfilling public policy objectives.”

The four performance standards are:
• [s]atisfy the customer in terms of cost, quality, and timeliness of the delivered product or service ...;
• [m]inimize administrative operating costs;
• [c]onduct business with integrity, fairness, and openness;
• [f]ulfill public policy objectives.
Contracting by Negotiation rules are in FAR Part 15

Government engages in discussions with prospective Contractor and allows opportunities to:

- Revise Cost Proposal
- Revise Technical Requirements
- Type of Contract (Cost Reimbursable/Firm Fixed Price)
- Contract Terms
“A firm-fixed price contract provides for a price that is not subject to any adjustment on the basis of the contractor’s cost experience in performing the contract. This contract type places upon the contractor maximum risk and full responsibility for all costs and resulting profit or loss. It provides maximum incentive for the contractor to control costs and perform effectively and imposes a minimum administrative burden upon the contracting parties.”

-FAR 16.202-1
Firm Fixed Price:

Contractor is paid a fixed unit price for a fixed number of inspections.

- Firm Price for each inspection type
- Payment is made upon completed and delivered work according to the terms of the contract.
- Payment cannot be made for items not previously negotiated such as increased number of inspections, travel/training, etc.

OTHER CONTRACT TYPES:
- Cost Reimbursement
- IDIQ Contract type: Can provide greater flexibility in terms of # of required inspections (Min/Max)
- Time and Material/Labor Hour – Least preferred type
- Incentive
ROLES AND RESPONSIBILITIES

- **Contracting Officer (CO):**
  Solicits and acquires goods/services, negotiates, and reviews Contractor requests for approval; only person authorized to approve changes to any of the terms and conditions of the contract, including cost/price adjustments

- **Contract Specialist**
  Solicits and acquires goods/services under direction of CO and engage in negotiations, also assists with contract administration

- **State Representative (FDA District Office)**
  Trains and verifies the performance of state inspectors assigned to audit contract inspections which are conducted by state inspectors

- **FDA District Office (DO) representatives:**
  - Conduct work planning sessions with the state employees to identify firms that require inspection.
  - Verify accuracy and completeness of inspection reports and other deliverables.
  - Involved in training and auditing inspectors performance
Roles & Responsibilities

Contracting Officer Representative

*Responsible for the administration of technical details within the scope of work and inspection, acceptance of deliverables and reports*

**CORs Do Not have the delegated authority to negotiate, enter into, change, or terminate contracts.**
“Early, frequent, and constructive engagement with industry leads to better acquisition outcomes.”

- FDA District Representatives determine number of inspections prior to RFP posting on FBO.
  - Districts look at work plan, firm inventory, and available FDA inspector and state resources

- FDA District/OP COR – Conduct meetings with each individual State prior to proposal submissions (clarifications, ensure meeting of mind).

- 2016/17 SOW incorporated certain State recommendations

- Continue early engagement in future in concert with AFDO and States
Communications PRIOR to Issuance of Solicitation

- Improve understanding of Government requirements and industry (State) capabilities, allowing offerors to judge whether or how they can satisfy the Government’s requirements.

- Enhances Government’s ability to obtain quality supplies and services and increases efficiency in proposal preparation, proposal evaluation, negotiation, and contract award.

- Any exchange of information must be consistent with procurement integrity (FAR 3.104).

- Techniques to promote early exchanges of information:
  • Industry or small business conferences
  • One-on-one meetings with potential offerors
  • Requests for Information (RFIs)/Pre-solicitation or Pre-Proposal conferences

Communications AFTER Issuance of Solicitation

- Every offeror must be provided with same information.
- CO is sole representative of the Government regarding communications with industry.
- Communications between the Government and the Offerors are extremely limited.
The Notice of Grant Award

*Legally binding document that:*

- Establishes funding level;
- Establishes period of support;
- Sets forth terms and conditions.

- **GOVERANCE**
  - Code of Federal Regulations
  - OMB Circulars
  - HHS Grants Administration Manual
  - HHS Grants Policy Statement
Federal Financial Assistance: Application to Award

1. Announcement Opens/Closes
2. Policy Consultation
3. Primary Screening (GMS)
   - Accept
   - Reject
     - Incomplete
     - Not Responsive
4. Secondary Screening (PO)
   - Accept
   - Reject
   - Not Responsive
5. Objective Review (GMO/PO/Comm.)
   - Approve
   - Disapprove
6. Award Decision (Award Packet)
   - Approve
   - Disapprove
7. CGMO
8. NOA
9. Applicant Notification
10. AO
11. CGMO
12. Results Must be certified by CGMO 1st
13. Applicant Notification

Results Must be certified by CGMO 1st

Announcement Opens/Closes

Primary Screening (GMS)

Secondary Screening (PO)

Objective Review (GMO/PO/Comm.)

Award Decision (Award Packet)

CGMO

NOA

Applicant Notification

AO

Applicant Notification

Results Must be certified by CGMO 1st

Announcement Opens/Closes

Primary Screening (GMS)

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Objective Review (GMO/PO/Comm.)

Award Decision (Award Packet)

CGMO

NOA

Applicant Notification

AO

Applicant Notification

Results Must be certified by CGMO 1st
<table>
<thead>
<tr>
<th>TYPE</th>
<th>ACTIVITY</th>
<th>PROJECT No.</th>
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<tr>
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<td>Project Title: Designing a VNFRPS Funding System in Support of a National IFSS</td>
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<td></td>
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<td>Project Title: 2015 AFDO Annual Conference</td>
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RESOURCES

Federal Acquisition Regulation (FAR)
https://www.acquisition.gov/?q=browsefar

Health and Human Services Acquisition Regulation (HHSAR)
http://www.ecfr.gov/cgi-bin/text-idx?SID=12201679706e1fde6cbadca3c3072496&mc=true&tpl=/ecfrbrowse/Title48/48chapter3.tpl

Grant Policy Statement
Questions?