

How to Become an MDDAP

Appraiser



The Voluntary Improvement Program (VIP) was developed with FDA, MDIC and industry. VIP offers medical device manufacturers a structured framework for enhancing quality and patient safety with a tailored version of the Capability Maturity Model Integration (CMMI) called the Medical Device Discovery Appraisal Program (MDDAP).

MDDAP certified appraisers drive the process. All are trained in the MDDAP, developed by ISACA to help manufacturers improve device quality, speed to market, and regulatory compliance, while reducing risk and inefficiency.





## Why Become an MDDAP Appraiser?

As an MDDAP Appraiser, you'll do more than assess companies, you'll empower them to build quality into every process, accelerate innovation and reduce risk. The MDDAP credential sets you apart as an expert in continuous improvement, and it can pay for itself in the first year.

- You'll advance your career with specialized training and high-impact work.
- You could earn up to \$200k/year.
- You'll develop recurring revenue streams with existing clients.
- You'll develop a reputation as a trusted advisor and industry thought leader.
- You'll contribute to a global movement toward better, safer medical devices.

## The Pathway

MDDAP certification entails a mix of coursework, observation and apprenticeship

COURSE: BUILDING
ORGANIZATIONAL CAPABILITY
LOCATION: ONLINE OR IN PERSON
COST: VARIABLE, US\$2,500 +/-

A 4-day introductory course where students learn to use CMMI to cultivate organizational capability in:

- Developing and engineering products
- Delivering and managing services
- Selecting and managing suppliers
- Managing data
- Managing people
- Managing safety and security

COURSE: MDDAP CONCEPTS
LOCATION: ONLINE SELF-PACED
COST: US\$2,500

A series of interactive, self-paced online modules that prepares learners to conduct an MDDAP appraisal and report the results. Learners complete this course prepared to schedule their observations.

COURSE: MDDAP APPRAISAL TEAM LEAD (ATL) TRAINING

**LOCATION: ONLINE SELF-PACED** 

COST: US\$5,000

Prepares learners to lead an MDDAP appraisal, after which they may schedule their ATL observations. The course covers:

- Appraisal quality and ethics
- Roles and responsibilities of appraisal participants
- Using the MDDAP Method Definition Document (M-MDD)
- Using MDDAP appraisals to evaluate and improve business performance
- Key aspects of the MDDAP appraisal approach

COURSE: MDDAP OVERVIEW LOCATION: ONLINE, SELF-PACED

**COST: US\$500** 

For CMMI certification holders only, this prerequisite course covers the fundamentals of the Voluntary Improvement Program (VIP).

- Background, stakeholders, purpose and value of VIP
- MDDAP program process, adoption and impact
- Key differences between an MDDAP appraisal and a typical inspection or audit

**OBSERVATION: ATM** 

LOCATION: VIRTUAL OR ON-SITE

**APPRAISAL** 

COST: US\$5,000

**OBSERVATION: ATL** 

**LOCATION: VIRTUAL OR ON-SITE** 

**APPRAISAL** 

COST: US\$15,000

In-the-field evaluation of a candidate applying the knowledge and skills to conduct an appraisal.

**APPRENTICESHIP** 

**LOCATION: VIRTUAL OR ON-SITE** 

**APPRAISAL** 

**COST: NONE, PAID APPRENTICESHIP** 

On the job training with a coach in preparation to become a qualified ATM or ATL. Apprentices typically conduct one to four appraisals.



## BECOME A MDDAP APPRAISAL **TEAM MEMBER Program Application Program Interview Building Org Capability Practitioner Exam MDDAP Concepts Professional Services Agreement ATM Observation Apprenticeship 1-4 Appraisals**



After MDDAP ATM certification. 3 year certification period, supersedes MDDAP ATM certification.

COURSE: MDDAP BOOTCAMP LOCATION: VIRTUAL AND ON-SITE COST: US\$30,000

Full learning Appraisal Team Lead journey from Building Organizational Capability through your Appraisal Team Lead Apprenticeship.

# Save 15% on the MDDAP Bootcamp!

The MDDAP Bootcamp covers all the courses, prep materials and exams you'll need to become fully MDDAP certified. Start your training and start saving today!

Visit isaca.org/vip to get started.

3 year certification period.

## MDDAP APPRAISAL TEAM MEMBER (ATM) ELIGIBILITY REQUIREMENTS

- · Proficiency in English
- Proficiency in technology
- 2+ years' experience in developing a product
- Experience with one or more of the following:
  - Working in teams
  - Facilitating group discussions (ability to follow threads as well as refocus the conversation)
  - Managing KPIs or other data
  - Evaluating people, products, or other work

#### **DESIRED EXPERIENCE**

- Coachable and self-aware, not quick to judge
- Detail-oriented and studious
- Able to break down complex topics into easy-to-understand language
- Excellent time manager
- Professional values and demeanor
- Experienced in any of the following:
  - Project management
  - Medical devices or regulated markets
  - Experience in providing a service
- Available for multiple one-week engagements throughout the year
- Able to work in the U.S. (citizenship, work visa, green card, etc.)

#### RENEWAL CRITERIA

(over a three-year certification period)

- Attend 50% of the MDDAP Appraiser Meetings
- Participate on an average of one appraisal per year
- No active quality complaints or investigations
- No outstanding payments
- No outstanding policy violations
- Meet MDDAP appraiser averages in performance and quality metrics

## MDDAP APPRAISAL TEAM LEAD (ATL) ELIGIBILITY REQUIREMENTS

- Proficiency in English
- Proficiency in technology
- 8+ years' experience in developing a product
- Serve on 5 MDDAP Appraisals as an ATM
- Be in good standing as an MDDAP ATM
- Experience with one or more of the following:
  - Leading teams or teaching students
  - Facilitating group discussions (ability to follow threads as well as refocus the conversation)
  - Project management

#### **DESIRED EXPERIENCE**

- Coachable and self-aware, not quick to judge
- Detail-oriented and studious
- Able to break down complex topics into easy-to-understand language
- Excellent time manager
- Professional values and demeanor
- Experienced in any of the following:
  - Medical devices or regulated markets
  - Identifying and mitigating risks and COIs
  - Managing logistics (e.g., travel, virtual meetings)
  - Managing conflicts to resolution
  - Experience in providing a service

- Available for multiple one-week engagements throughout the year
- Able to work in the U.S. (citizenship, work visa, green card, etc.)

#### **RENEWAL CRITERIA**

(over a three-year certification period)

- Attend 50% of the MDDAP Appraiser Meetings
- And lead an average of 1 appraisal per year
- No active quality complaints or investigations
- No outstanding payments
- No outstanding policy violations
- Above-average MDDAP appraiser performance and quality metrics
- If applicable, complete an average of one observation or coaching per year

MDDAP appraisals are much more interactive than other programs. In my experience, most individuals want to improve, but especially in inspections, many individuals are more guarded and afraid of saying too much. With MDDAP, you can be open and honest without fear. You are also getting a more holistic view of your organization's systems, which can help improve your compliance in ways that may not have been visible otherwise."

> Sue Hibbeln VP, Quality and Regulatory Affairs Lumos Diagnostics

"My primary goal in adding MDDAP service offerings to my portfolio stems from a wholehearted belief in the program's foundation. By providing sites with the opportunity to examine their challenges without the pressure of targets or scores, and by gathering insights directly from their own teams, the program fosters a shared understanding of issues, builds genuine buy-in for desired changes, and supports the development of tailored improvement paths that truly make sense for each site."

Becky Fitzgerald
Principal and Co-Founder
Two Harbors

So many of the MDDAP clients I have worked with over the past 5-6 years have transformed certain aspects of their business. It is so rewarding to come back year after year and see how the opportunities coming out of the appraisals have been acted upon and have since become institutionalized."

Beth Layman
Principal Partner
Layman & Layman