Purpose

The purpose of this form is to communicate the requirements, roles, timelines, and expectations regarding the Independent Course Delivery (ICD) Application Package.

ICD Application Package Contents

This ICD Application Package contains the following:

General ICD Application Forms:
- Application for Independent Course Delivery (ICD) Form
- Student Registration Form (for ICD students)

Forms Needed for TTT Participation:
- Career Biography Template
- Student Registration Form (for TTT students)

Instructions for Initial Submission of the ICD Application Package

To begin the ICD Application process:

The following steps must be completed at a **minimum of 12 weeks prior to the desired course delivery** (although OTED recommends completing them as early possible, ideally at least five months prior to the desired course delivery).

1. Complete the following ICD Application Package components:

    - Application for Independent Course Delivery (ICD) Form

    If you are proposing instructors for this ICD that do not yet have Qualified Instructor (QI) status for the desired course, the following forms are also required at this time:

    - Career Biography/CV

        NOTE: One Career Biography or CV must be submitted for each proposed ICD instructor.

        NOTE: You are not required to use the provided Career Biography Template to create your Career Biography/CV; however, the elements specified in the template should be included in the Career Biography/CV submitted (e.g. education, subject matter experience relevant to the course objectives, adult learning experience, etc.)

    - Student Registration Form (for TTT participants)

> *NOTE: One copy of the Student Registration Form must be submitted for each proposed ICD instructor.*

2. Submit all components together to the OTED ICD Program Administrator (ICD PA) via email at ORAOTEDICDAdmin@fda.hhs.gov.

> *NOTE: The ICD Applicant is responsible for compiling and submitting all ICD Application Package components to the OTED ICD PA. Do not direct instructors or students to send information directly to OTED unless requested by the OTED ICD PA.*

> ***Your course is NOT approved for delivery until you receive a formal Application Approved Notice from OTED.***

Requirements for Application Approval

After your ICD Application Package has been processed, you must complete the following steps in order to obtain full application approval:

1. You (the ICD Applicant Point of Contact (POC)) must participate in a Course Logistics Review Call with FDA OTED. The OTED ICD PA will contact you to schedule this call.

> *NOTE: You may invite your ICD Instructors to attend this call; however, their attendance is not required.*

2. You must verify that the course prerequisites have been completed for each student that will be in attendance.

> *NOTE: You are responsible for verifying prerequisite completion as well as maintaining student records after the completion of the ICD.*

Submission Checklist

Prior to your initial submission of the ICD Application Package, you must confirm that all of the following forms have been completed and submitted.

Documents Required for All ICD Applications:

☐ Application for ICD Form (all pages)

Documents Required When Proposed Instructors do not Yet Have QI Status:

☐ Career Biography/CV (one per proposed instructor)

☐ Student Registration Form (for TTT participants) (one per proposed instructor)

Application Timelines

The following timeline outlines the approximate timeframes for each step of the application process:

- **Day 0:** The ICD Applicant submits the ICD Application Package to the OTED ICD PA.

- **Day 2 (or sooner):** The ICD PA sends the ICD Applicant an email confirmation that the ICD Application Package has been received and is under review.

- **Day 10 (or sooner):** The ICD PA completes review of the ICD Application Package and sends the ICD Applicant an email confirmation indicating either that the ICD Application Package has been processed or that further information is required.

- **Day 24 (or sooner):** The ICD PA facilitates the Course Logistics Review Call with the ICD Applicant. During this call, both parties will confirm that the course logistical requirements will be met.

- **Day 31 (or sooner):** The ICD PA sends the ICD Applicant an email confirmation indicating that either the ICD Application Package has been formally approved, or that additional action is necessary.

- **8 weeks prior to the ICD (or sooner):** The ICD PA facilitates the "Course Content Review Call" with the ICD Applicant and instructors to review the course materials and ensure there are no further questions or needs.

For further assistance please contact the ORA OTED ICD Program Administrator (ICD PA) at ORAOTEDICDAdmin@fda.hhs.gov.

Directions

The purpose of this form is to document information associated with a requested Independent Course Delivery (ICD) of an OTED training course, confirm the Point of Contact (POC) of the ICD Applicant, and verify the ICD Applicant's agreement to adhere to OTED's ICD policies.

- You must complete *all* pages of this form and submit at least 12 weeks prior to desired course delivery.

- Select the **Validate** button on the final page to confirm that all required fields have been completed. If any required fields have not been completed, a system message will appear indicating which fields still require an entry.

- If at any time you wish to delete all content you have provided and reset this form to its original state, select the **Clear** button on the final page.

  o *Note: Clearing the form is irreversible.*

FDA Training Course Requested for Delivery

The following identifying information for the FDA training course selected for this proposed ICD must be provided below:

FDA Course Number *(ex. FD190)*	**Title** *(ex. Food Current Good Manufacturing Practice, Application, and Evidence Development)*

Proposed Delivery Information

The following information for the proposed Independent Course Delivery (ICD) must be provided below:

Proposed Training Location		
Name of Facility/Location		
Street		
City	State	Zip
Proposed Training Start Date	**Proposed Training End Date**	**Anticipated Number of Students**

Instructor Information

The following information for the identified ICD Instructors for this proposed Independent Course Delivery (ICD) must be provided below:

Instructor Name Last Name	First Name
Instructor Email	Has OTED granted this individual Qualified Instructor (QI) status for this course? ☐ Yes ☐ No

Instructor Name Last Name	First Name
Instructor Email	Has OTED granted this individual Qualified Instructor (QI) status for this course? ☐ Yes ☐ No

Instructor Name Last Name	First Name
Instructor Email	Has OTED granted this individual Qualified Instructor (QI) status for this course? ☐ Yes ☐ No

Instructor Name Last Name	First Name
Instructor Email	Has OTED granted this individual Qualified Instructor (QI) status for this course? ☐ Yes ☐ No

Instructor Name Last Name	First Name
Instructor Email	Has OTED granted this individual Qualified Instructor (QI) status for this course? ☐ Yes ☐ No

Agreements

By submitting this form, I/my agency is requesting an Independent Course Delivery (ICD) of the course listed on Page 1 of this application and agree to the following (check "yes" or "no" for each statement):

1. I confirm the date of the proposed course delivery is at minimum 12 weeks after the date of submission of this form.

   ☐ **Yes** ☐ **No**

2. I acknowledge FDA as the official sponsor for this course.

   ☐ **Yes** ☐ **No**

   a. If the course will be offered by another entity on behalf of the requestor, all advertisements and announcements must note the course is an FDA course being held at their facility.

3. I understand that my agency and the ICD Instructors:

   ☐ **Yes** ☐ **No**

   a. Must not delete or alter content from the original course material.

   b. Must deliver the course in accordance with the facilitation guidance provided within the Instructor Guide without deviation.

   c. Must fully cover all course content that has been provided.

   d. Must adhere to the course equipment, supply, and facility requirements provided by OTED.

   e. Must discuss any proposed deviations or substitutions from the course's equipment, supply, and facility requirements with OTED and obtain approval during the Course Logistics Review Call.

4. I/my agency will retain the following information and items after completion of the course, and understand that OTED could request this information in the future:

   ☐ **Yes** ☐ **No**

   a. Daily Sign-In Sheet: A copy of the *Daily Course Sign-In Sheet* with signatures from all participants is needed to confirm attendance.

   b. Course Records/Artifacts: All pertinent course records and artifacts must be retained for verification of student success.

5. (If applicable to course and provided by OTED) I/my agency will promptly return the Course Equipment Kit after completion of the course.

   ☐ **Yes** ☐ **No**

a. **PLEASE NOTE:** If there are any materials that are damaged beyond repair, lost, or stolen, the agency requesting the course is responsible for paying any cost to replace the materials.

6. I understand that enrollment of participants for this training course will include state, local, tribal, or territorial regulatory partners within my agency's jurisdiction, but seats may be offered to participants from neighboring jurisdictions and the FDA.

☐ **Yes**   ☐ **No**

7. I understand that this proposed course is not approved for delivery until I/my agency receives a formal *Application Approved Notice* from FDA OTED.

☐ **Yes**   ☐ **No**

Point of Contact (POC) Information

The following information for the identified Point of Contact (POC) for this proposed Independent Course Delivery (ICD) must be provided below:

Point of Contact Last Name	Middle Initial	First Name	
Agency			
Email		Phone	
Complete Mailing Address Street			
City	State	Zip	

Point of Contact (POC) Signature

The identified ICD Applicant Point of Contact (POC) for this proposed ICD must provide their name, signature, and date of form submission below.

Name	Date
Signature	

(Electronic signature accepted with date and time stamp)

Secondary Official Signature (if required)

This is a secondary managerial signature (if required)

Name	Date
Signature	

(Electronic signature accepted with date and time stamp)

Please submit this completed form along with all other components of the ICD Application Package to the FDA OTED ICD Program Administrator (ICD PA).

For further assistance please contact the ORA OTED ICD PA at ORAOTEDICDAdmin@fda.hhs.gov.

Background

Purpose

FDA and non-FDA staff involved in the design, development, delivery, and evaluation of learning events are required to be:

- Qualified to perform their assigned tasks

- Current in the subject matter and learning methods

OTED uses the Career Biography to document compliance with this requirement.

Important Notes

- A Career Biography needs to be completed by anyone who directly contributes to the Analysis, Design, Development, Implementation, and Evaluation of OTED courses. This includes both FDA and non-FDA staff (Course Advisory Group (CAG)/Subject Matter Experts (SMEs), Training Officers (TOs), Instructors, and Instructional Systems Specialists (ISSs)).

- It is not necessary to document every job or educational experience you have had. **Only document those positions and experiences that qualify you** to develop, instruct, or support a particular module, lesson, or activity in the course.

- Do NOT put any private or protected information in your Career Biography.

Records Management

Career Biographies are official OTED records. If you are not an OTED employee, please send your Career Biography to your OTED ICD Program Administrator (ICD PA).

Template Use

The following pages contain a Career Biography template. You are not required to use this template, but the elements specified in the template should be included in the Career Biography you submit.

Notice that the template contains boxes with guidance for completing the Career Biography. **Whether using the template or your own personal format**, the guidance boxes should be reviewed, as they contain details pertaining to the information OTED seeks in a submitted biography.

Education

Please include Undergraduate and Graduate Degree information.

Discipline: _____

Degree: _____

Institution: _____

Discipline: _____

Degree: _____

Institution: _____

Discipline: _____

Degree: _____

Institution: _____

Discipline: _____

Degree: _____

Institution: _____

Professional and Adult Learning Experience (Brief)

Subject Matter Experience

Include examples of your expertise related to the desired course's Terminal Learning Objectives (TLOs), such as industry experience, material development, etc. The TLOs for the desired course can be found within OTED's Pathlore Learning Center. **Provide dates** where possible.

Specific examples of the types of items that could be included are provided below.

- Commodity-specific work experience (e.g., types of inspections, regulatory actions resulting from that work, etc.)

- Commodity-specific knowledge resulting in program expert/national expert status

- Content-specific presentations

- Course-specific mentoring (received or conducted)

- Course-specific on-the-job training (received or provided)

- Publications (authored individually or collaboratively)

- Attendance of the base course you are seeking qualification to teach

Adult Learning Experience

Include those items **related to adult learning and/or instructional competencies**. Provide **delivery locations, dates, and formats** when possible. Examples of the types of items that could be included are provided below.

- Past course deliveries

- Course completions

- Course design experience

- Conferences (attended or presented, panel participation, etc.)

- Webinars (attended or presented)

- Trainings (attended or presented)

- Curriculum analysis

- Assessment development (i.e., classroom exercises, case studies, exams, etc.)

Certifications/Awards

- _____

- _____

- _____

- _____

- _____

- _____

- _____

- _____

- _____

- _____

- _____

- _____