

Tap into the global resources of the Locum Group and we'll look after your FDA Development needs. We offer quality know-how technology to discerning clients world wide.



In addition you can have access to the wider opportunities of international drug development through our know-how technology which are provided on a discretionary and confidential basis.

Our current know-how portfolio can be specifically tailored to suit your update and development requirements for product growth and diversity. All data handled by our dedicated team of development scientists.

IAGIM

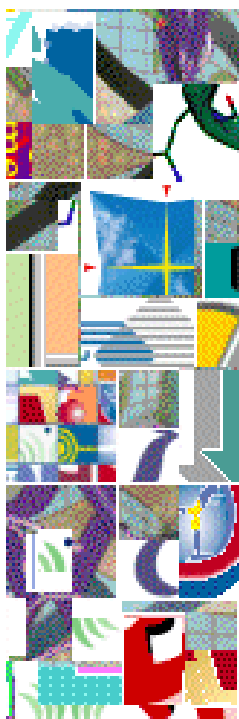


FDA UPGRADE PROGRAM

IAGIM - FDA UPGRADE PROGRAM



IAGIM's FDA program consists of six stages over a period of three years. The upgrade stages, after a detailed and thorough departmental review of the company's objectives and vision statement, are split into three levels of achievement. Each subsequent level is more advanced than the previous level.



FIRST YEAR - LEVEL ONE

- STAGE 101. SOPs
- STAGE 102. All Documentation (incl. IQOQ)
- STAGE 103. cGMP and facilities
- STAGE 104. Analytical Laboratory
- STAGE 105. Production and Process Validation
- STAGE 106. Manufacturing and Training .

SECOND YEAR - LEVEL TWO

- STAGE 201. SOPs
- STAGE 202. All Documentation (incl. IQOQ)
- STAGE 203. cGMP and facilities
- STAGE 204. Analytical Laboratory
- STAGE 205. Production and Process Validation
- STAGE 206. Manufacturing and Training.

THIRD YEAR - LEVEL THREE

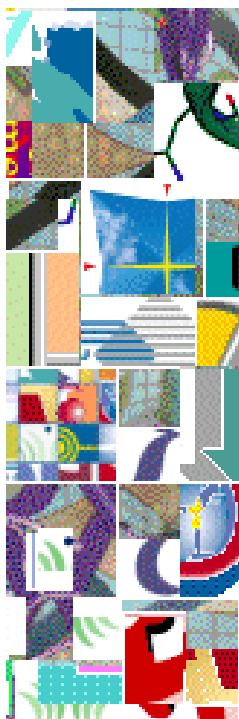
- STAGE 301. SOPs
- STAGE 302. All Documentation (incl. IQOQ)
- STAGE 303. cGMP and facilities
- STAGE 304. Analytical Laboratory
- STAGE 305. Production and Process Validation
- STAGE 306. Manufacturing and Training.



IAGIM - FDA UPGRADE PROGRAM

PROGRAM TOOLS

The Three year Program is detailed and exhaustive. The program meets all current FDA requirements which include:



- ≡ Key Documentation (PDF and Word RTF - for in-house modification and customization).
- ≡ Audio Short Courses.
- ≡ PowerPoint Explanations, Seminars and Presentations.
- ≡ Email Q&A - Daily Questions and Answers.
- ≡ Executive Summary & Progress Reports, Evaluation Graphs and Tables.
- ≡ Bimonthly Management Overviews and Executive Reports.
- ≡ Special Access to a dedicated IAGIM Website monitoring firm's FDA update progress.
- ≡ Accounts Department Bulletin Board with monthly update Summary.
- ≡ Onsite and/or Off-site 10day intensive annual Workshops and Focus Groups for each of the THREE years.

COST STRUCTURE

- Includes all documentation (IQOQ, SOPs, Model Assays, PAI Check List, Handbooks, Programs, Expert Consultation, Reports, etc.) Mandatory 3 to 5 Year IAGIM Membership.

PROGRAM UPGRADE FEE (USD\$)			
STAGE	Monthly Payment includes all key documentation	Per year Excludes Annual 10 day Workshop	10 day Open Work Shop - 2 x 5 days (conference venues on web) www.iagim.org/workshops.php3
First Year	\$1 500	\$18 000	\$6 500
Second Year	\$1 850	\$22 200	\$6 500
Third Year	\$1 950	\$23 400	\$6 800
TOTAL	--	\$63 600	\$19 800

This Global IAGIM FDA Program is supported and funded by the donations and private contributions of US BIRD Foundation, Locum Bilateral US Foundation and IAGIM Research Foundations. Membership to a 3 - 5 Year IAGIM Benefits Program is mandatory. www.iagim.org