INTEGRALAB® ONE
EASY GMP - EASY FDG
INTEGRALAB®ONE  EASY (C)GMP - EASY FDG

YOUR READY-TO-RUN RADIOPHARMACY

1. **BUILD**
   - GMP LAYOUT
   - DETAILED ROOM DATA SHEETS AND ASSOCIATED SET OF DRAWINGS
   - DEFINITION AND DIMENSIONING OF UTILITIES (HVAC, ...)

2. **EQUIP & INTEGRATE**
   - CYCLONE® KUBE
   - 2 NIRTA® CONICAL TARGETS
   - 2 SYNTHERA® AND 1 DISPENSING IN 1 KITCELL
   - COMPACT QUALITY CONTROL
   - RADIATION MONITORING
   - LAB EQUIPMENT

3. **TRAIN AND VALIDATE**
   - START-UP TRAINING ON EQUIPMENT
   - FILE FOR (C)GMP CERTIFICATION:
     - VALIDATION MASTER PLAN
     - QUALITY RISK MANAGEMENT
     - SITE MASTER FILE
     - TEMPLATE DOCUMENTATION FOR PHARMACEUTICAL QUALITY SYSTEM INCLUDING BATCH RECORDS & SOPs.

4. **OPERATE**
   - DETAILED LIST OF MATERIAL PROVIDED:
     - PRODUCTION & QC CONSUMABLES
     - FACILITY OPERATION/CLEANING CONSUMABLES
     - RECOMMENDED SPARE PARTS LIST
     - IBA EQUIPMENT MAINTENANCE
     - EQUIPMENT WARRANTY.

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**INVESTMENT CAPEX**
- Pre-operating expenses
- Capitalized financial costs
- Project development
- Laboratory equipment
- IBA services
- Building

**OPEX BREAKDOWN**
- Quality control
- Production consumables
- General & administration
- Certification / inspection
- Power
- Equipment spare parts
- Equipment & facility maintenance
- Production staff

* Ask for your personalized business plan

**REDUCED PROJECT TIME**

**FASTER RETURN ON INVESTMENT**

**PRODUCTION CAPACITY**

- **RUN DURATION**
  - **CURRENT** (h)
  - **MAX TARGET** (h)
  - **FDG SYNTHERA® Doses**
  - **DOSES**
  - 1h: 50
  - 2h: 6
  - 1h: 100
  - 2h: 10
  - 1h: 150
  - 2h: 10

**TYPICAL PRODUCTION STAFF**
- 1 QUALIFIED PERSON
- 1 SITE MANAGER
- 2 PRODUCTION OPERATORS
- 1 QC OPERATOR

**LIMITED ENVIRONMENTAL IMPACT**
- REDUCED FACILITY FOOTPRINT
- 20% TO 50% LESS POWER CONSUMPTION WITH THE CYCLONE® KUBE
- ADVANCED TECHNOLOGY ON SPECIAL TECHNIQUES DESIGN ADVICES TO MAXIMIZE THE ENERGY SAVINGS
- ENVIRONMENT FRIENDLY DESIGN AND MATERIAL SELECTION

**INTEGRALAB®ONE**
- REDUCED PROJECT TIME
- MAXIMIZED UPTIME
- STAY AHEAD OF TIME

<100 m²

1,070 ft² PET center area

APPROX
50 m²

APPROX
9.66 ft²/33 ft²

QUALITY CONTROL

FDG PRODUCTION LABORATORY

SELF-SHIELDED CYCLOTRON

1.000

1,500

2.000

2.500

3.000

3.500

Doses/quarter

TIME

0

500

1,000

1,500

2,000

2,500

3,000

3.000

3.500

Doses/quarter

TIME

0

500

1,000

1,500

2,000

2,500

3,000

3.000

3.500

Doses/quarter

BUILDING DESIGN CONSTRUCTION EQUIPMENT SELECTION & INTEGRATION VALIDATION CONSUMABLES PROCUREMENT PROJECT TIME

IBA services

BUILDING

EQUIPMENT

LAB EQUIPMENT

SELF-SHIELDED CYCLOTRON

QUALITY CONTROL

FDG PRODUCTION LABORATORY

APPROX
10.46 ft²/44 ft²

APPROX
9.66 ft²/33 ft²
INTEGRALAB® is a fully integrated solution, combining equipment and services for the establishment of radiopharmaceutical (c)GMP production centers. IntegraLab® includes, among others, the building design achieving full regulatory compliance and the selection, integration, supply, installation and qualification of suitable equipment to match the customer’s radionuclides production goals.

CYCLONE® KIUBE
Cyclone® KIUBE is a 18 MeV energy cyclotron that accelerates negative ions up to 18 MeV. It offers the most important success factors:

- Superior performance for operational and cost efficiency
- High reliability with embedded redundancy for the best uptime
- Best safety with low personnel exposure
- Real flexibility thanks to a full range of Nirta® targets.

SYNTHERA®
Synthera® is the MOST COMPACT multi-purpose automated synthesizer for the production of 18F-FDG, other 18F-labeled compounds (18F-CH, 18F-FLT, Na18F, 18F-MISO, 18F-DOPA, 68Ga peptides, ...) as well as radiopharmaceuticals. Synthera® is designed to accommodate a wide range of radiochemistry.

INTEGRALAB® ONE
THE MOST OPTIMIZED RADIOPHARMACY

REDUCED PROJECT TIME FOR A FASTER TIME TO MARKET
- Complete building file including special techniques
- (c)GMP qualification, validation and market authorization support
- Project totally coordinated by an experienced IBA project manager supported by a team of in-house experts.

MAXIMIZED UPTIME WITH BUILT-IN REDUNDANCY
- Two proton sources, Two 18F targets, Two strippers per target, Two Synthera® synthesizers
- 24/7 online support and fast spare parts delivery
- Cyclotron control system with automatic check of all parameters before production.

STAY AHEAD OF TIME with an upgradeable system
- Cyclotron capacity upgradeable from 100µA to 150µA
- 8 target exit ports on the cyclotron for production of other molecules
- Connection to a worldwide community of experts.
ABOUT IBA RADIOPHARMA SOLUTIONS

Based on longstanding expertise, IBA RadioPharma Solutions supports hospitals and radiopharmaceutical distribution centers with their in-house radioisotopes production by providing them global solutions, from project design to the operation of their facility. In addition to high-quality technology production equipment, IBA has developed in-depth experience in setting up GMP radiopharmaceuticals production centers.

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While all care has been taken to ensure that the information contained in this publication is correct, we accept no responsibility for any inaccuracy and reserve the right to modify this information. Technical specifications are based on standard operating conditions and may be subject to variations.

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