

INTEGRALAB[®] ONE

EASY GMP - EASY FDG

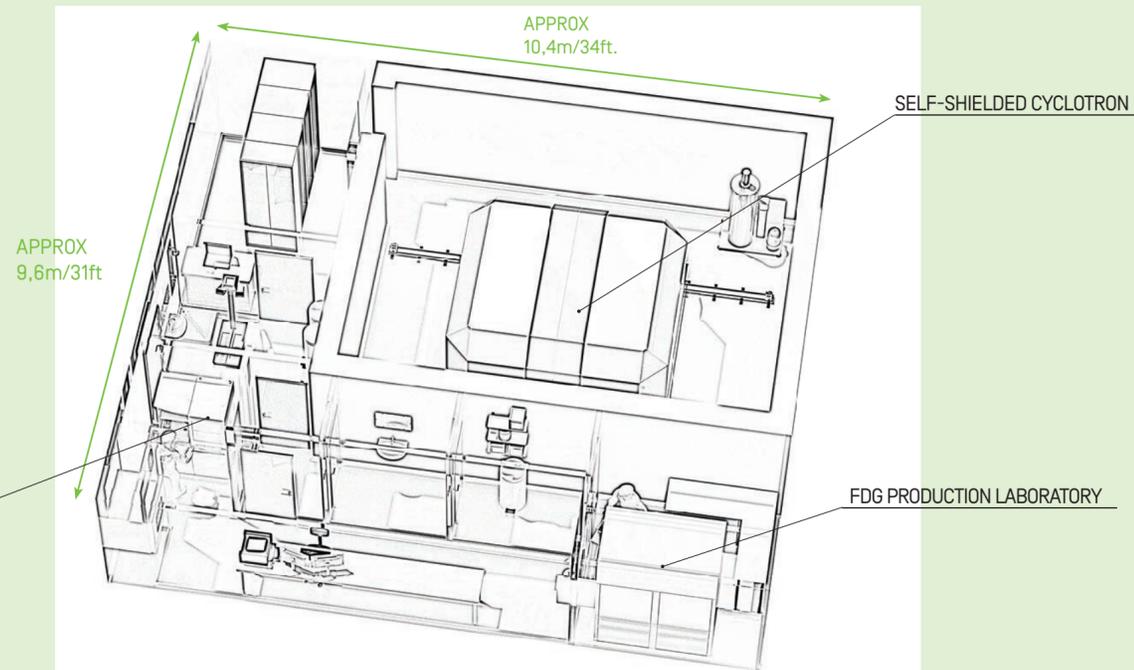
RADIO
PHARMA
SOLUTIONS

INTEGRALAB® ONE EASY (C)GMP - EASY FDG



< 100 m²

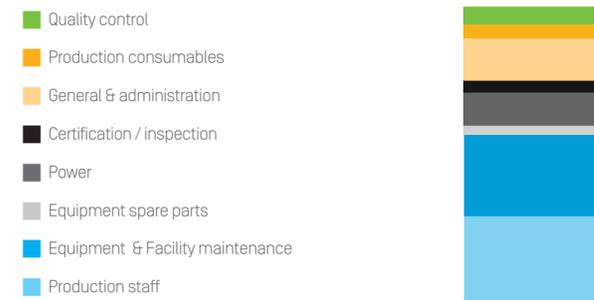
1,070 ft² PET center area



INVESTMENT CAPEX*



OPEX BREAKDOWN*



* Ask for your personalized business plan

PRODUCTION CAPACITY

RUN DURATION	CURRENT (μA)	MAX TARGET ACTIVITY (Ci)	FDG SYNTHERA® (Ci)	DOSES*
1h	50	3,6	2,2	21 - 36
2h		6	3,6	36 - 60
1h	100	6	3,6	36 - 60
2h		10	6	60 - 100
1h	150	9,6	5,8	58 - 96
2h		16	9,6	96 - 160

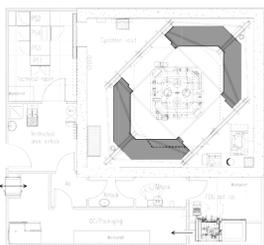
(* may vary according to local condition, transport time and patient schedule)

TYPICAL PRODUCTION STAFF



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® KIUBE
- 2 NIRTA® CONICAL TARGETS



- 2 SYNTHERA®+ AND 1 DISPENSING IN 1 HOTCELL



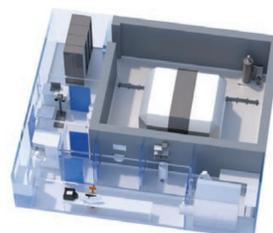
- COMPACT QUALITY CONTROL
- RADIATION MONITORING
- LAB EQUIPMENT

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

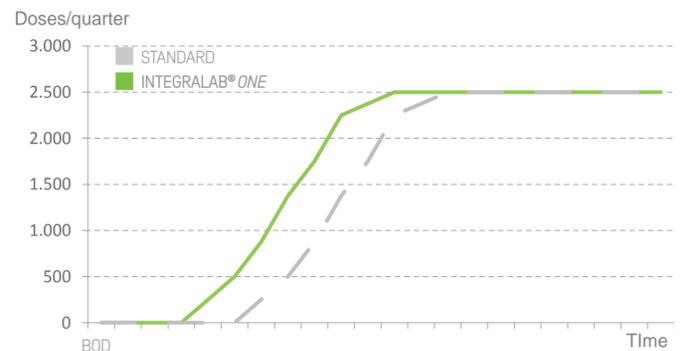


- DETAILED LIST OF MATERIAL PROVIDED :
 - PRODUCTION & QC CONSUMABLES
 - FACILITY OPERATION/CLEANING CONSUMABLES
 - RECOMMENDED SPARE PARTS LIST
- IBA EQUIPMENT MAINTENANCE
- EQUIPMENT WARRANTY.

REDUCED PROJECT TIME



FASTER RETURN ON INVESTMENT



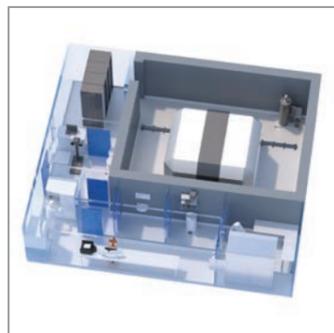
LIMITED ENVIRONMENTAL IMPACT



- REDUCED FACILITY FOOTPRINT
- 20% TO 50% LESS POWER CONSUMPTION WITH THE CYCLONE® KIUBE
- 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



INTEGRALAB®

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 radioisotopes 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 [¹⁸FCH, ¹⁸FLT, Na¹⁸F, ¹⁸F-Miso, ¹⁸F-DOPA, ⁶⁸Ga peptides, ...] as well as radiopharmaceuticals.

Synthera®+ is designed to accommodate a wide range of radiochemistries.

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 targets, 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.

CONTACT US

*Chemin du Cyclotron, 3
1348 Louvain-la-Neuve, Belgium
Tel.: + 32 10 201 275
Fax: + 32 10 47 59 58
Info-cyclo@iba-group.com*

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