

# INTEGRALAB<sup>®</sup> ONE

## EASY GMP - EASY FDG

RADIO  
PHARMA  
SOLUTIONS

# INTEGRALAB®ONE EASY (C)GMP – EASY FDG



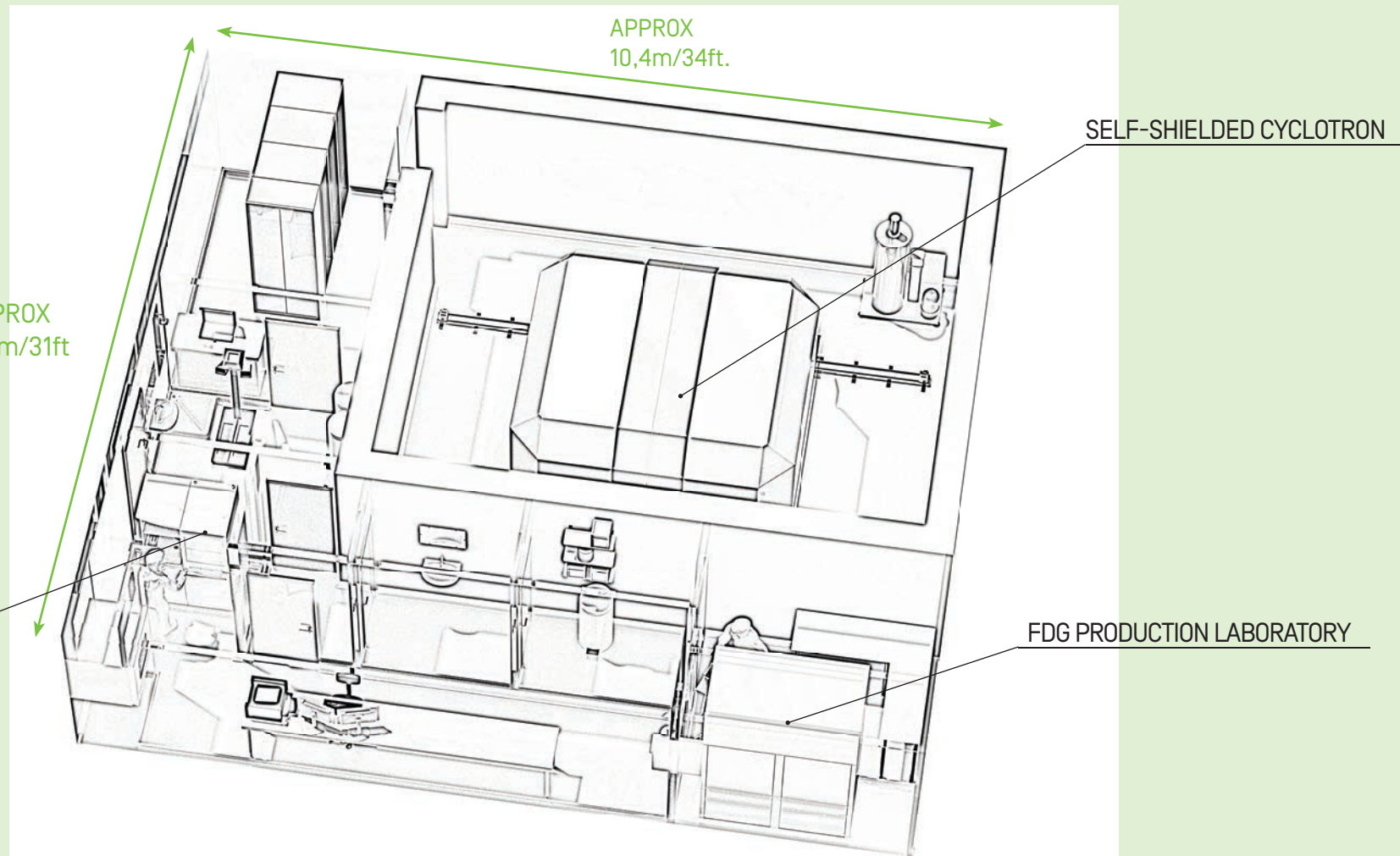
<100 m<sup>2</sup>

1,070 ft<sup>2</sup> PET center area

APPROX  
9,6m/31ft

APPROX  
10,4m/34ft.

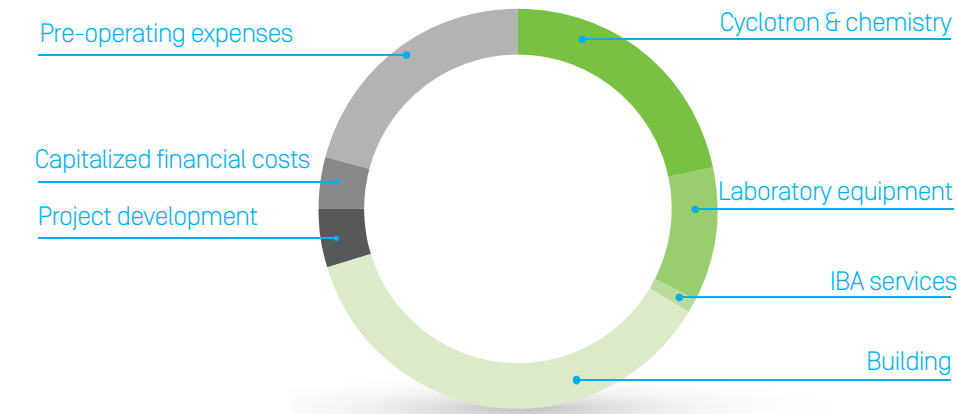
QUALITY CONTROL



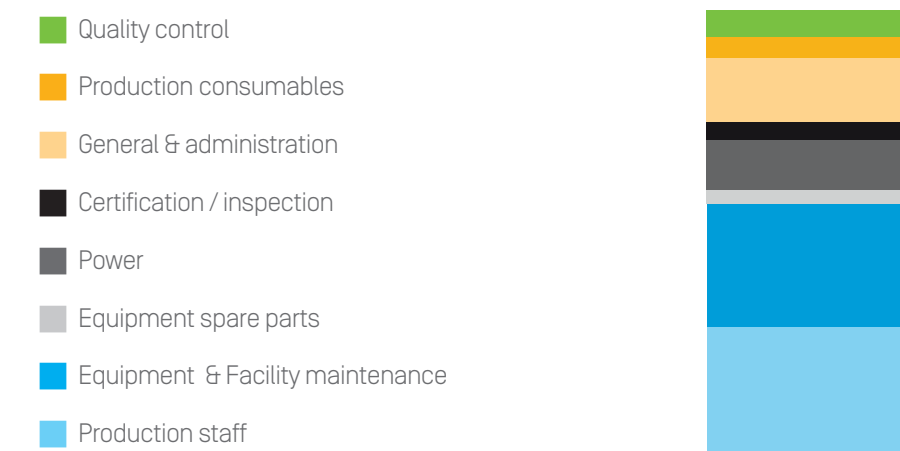
SELF-SHIELDED CYCLOTRON

FDG PRODUCTION LABORATORY

## INVESTMENT CAPEX\*



## OPEX BREAKDOWN\*



\* Ask for your personalized business plan

## PRODUCTION CAPACITY

RUN DURATION	CURRENT (μA)	MAX TARGET ACTIVITY (Ci)	FDG SYNTHESA® (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

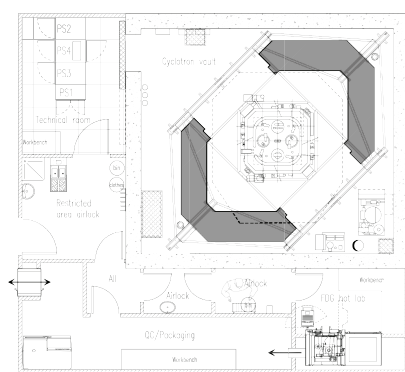
(\* may vary according to local condition, transport time and patient schedule)

## TYPICAL PRODUCTION STAFF



## YOUR READY-TO-RUN RADIOPHARMACY

### 1 BUILD



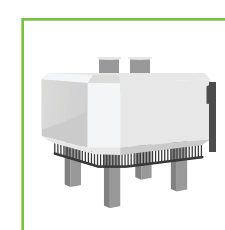
- GMP LAYOUT
- DETAILED ROOM DATA SHEETS AND ASSOCIATED SET OF DRAWINGS
- DEFINITION AND DIMENSIONING OF UTILITIES (HVAC, ...).

### 3 TRAIN AND VALIDATE

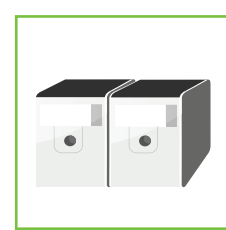


- START-UP TRAINING ON EQUIPMENT
- FILE FOR (C)GMP CERTIFICATION :
  - VALIDATION MASTER PLAN
  - QUALITY RISK MANAGEMENT
  - SITE MASTER FILE
  - TEMPLATE DOCUMENTATION FOR PHARMACEUTICAL QUALITY SYSTEM INCLUDING BATCH RECORDS & SOPS.

### 2 EQUIP & INTEGRATE



- CYCLONE® KIUBE
- 2 NIRTA® CONICAL TARGETS

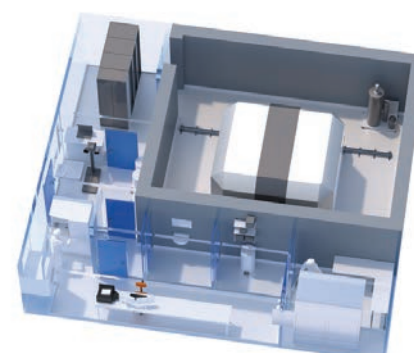


- 2 SYNTHRA®+ AND 1 DISPENSING IN 1 HOTCELL



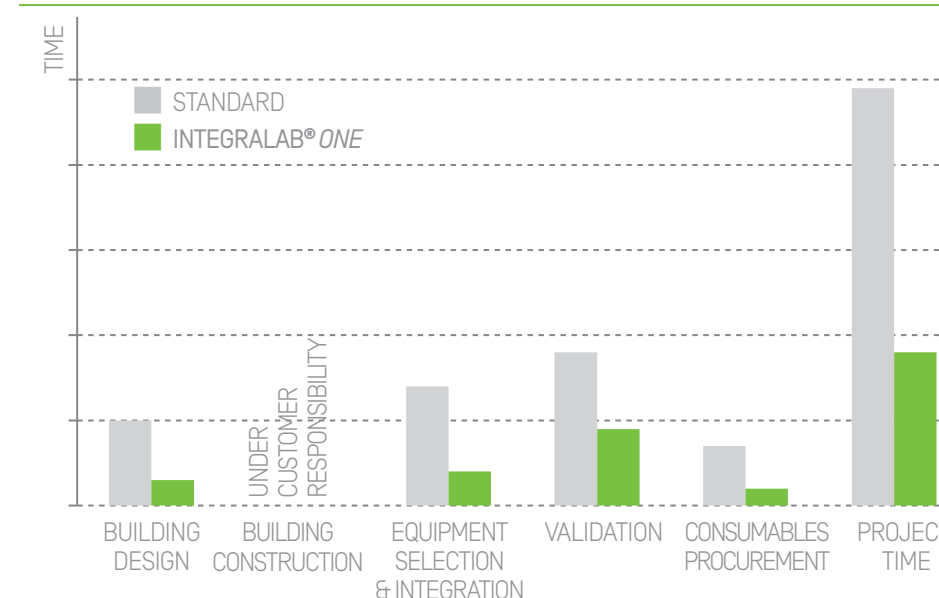
- COMPACT QUALITY CONTROL
- RADIATION MONITORING
- LAB EQUIPMENT

### 4 OPERATE

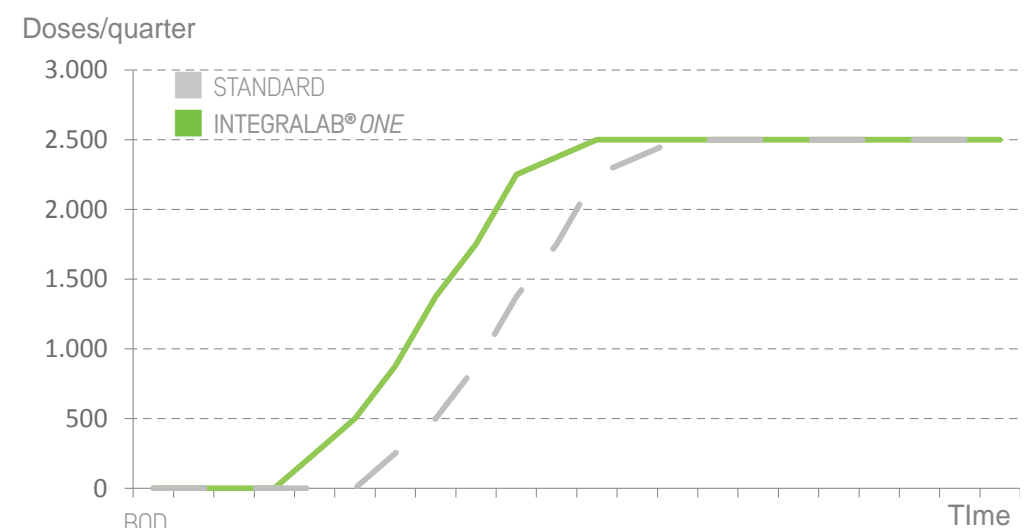


- DETAILED LIST OF MATERIAL PROVIDED :
  - PRODUCTION & QC CONSUMABLES
  - FACILITY OPERATION/CLEANING CONSUMABLES
  - RECOMMENDED SPARE PARTS LIST
- IBA EQUIPMENT MAINTENANCE
- EQUIPMENT WARRANTY.

## REDUCED PROJECT TIME



## FASTER RETURN ON INVESTMENT



## LIMITED ENVIRONMENTAL IMPACT



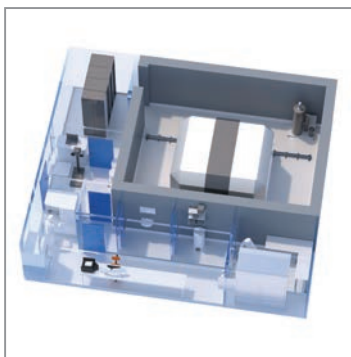
- REDUCED FACILITY FOOTPRINT
- 20% TO 50% LESS POWER CONSUMPTION WITH THE CYCLONE® KIUBE
- ADVANCED TECHNOLOGY ON SPECIAL TECHNIQUES DESIGN ADVICES TO MAXIMIZE THE ENERGY SAVINGS
- ENVIRONMENT FRIENDLY DESIGN AND MATERIAL SELECTION

## INTEGRALAB®ONE

- REDUCED PROJECT TIME
- MAXIMIZED UPTIME
- STAY AHEAD OF TIME

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### 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 <sup>18</sup>F-FDG, other <sup>18</sup>F-labeled compounds [<sup>18</sup>FCH, <sup>18</sup>FLT, Na<sup>18</sup>F, <sup>18</sup>F-Miso, <sup>18</sup>F-DOPA, <sup>68</sup>Ga 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 <sup>18</sup>F 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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