

# The IBA IntegraLab® Team Supports the Penn PET Center for cGMP Compliance

Louvain-La-Neuve, Belgium, June 7th, 2012 - IBA (Ion Beam Applications S.A.) announces that the University of Pennsylvania in Philadelphia (Penn) has chosen the IBA IntegraLab® team to provide consultancy support for cGMP compliance and for the ANDA dossier filing of its radiopharmaceutical production facility.

In compliance with FDA requirements Penn recently filed an ANDA for <sup>18</sup>F-FDG and is now operating in compliance with 21-CFR Part 212 (cGMP).

IBA will provide advice on cGMP compliance and on the submission of an amendment to the ANDA for an additional upgrade of the Penn radiopharmaceutical facility. This upgrade will include new hot cells as well as the relocation of some of its manufacturing equipment (including the IBA Synthera<sup>®</sup> synthesizer).

The IntegraLab® solution combines equipment and services allowing the establishment of a radiopharmaceutical production center with full regulatory compliance. IBA has a proven track record in this field, having recently completed major cGMP-compliant upgrades and submissions to the FDA of ANDAs for <sup>18</sup>F-FDG & <sup>18</sup>F-NaF in eleven of its US-based sites. In addition, IBA Europe has over fifteen radiopharmaceutical manufacturing and distribution facilities, with Marketing Authorizations for <sup>18</sup>F FDG and other molecules in the majority of these sites.

Based on that experience, Penn has chosen IBA as a key support in its regulatory program to meet FDA requirements. "We are happy to have IBA assist us as we continue to move forward in this challenging new regulatory environment," said Richard Freifelder, Ph.D, Cyclotron Facility Manager. "We have worked with IBA on a number of projects in the past and the combination of our Synthera Synthesis platform, Comecer Hot Cells, and our IBA Cyclone 18/9 offer us a unique opportunity to continue our long and fruitful relationship with IBA."

"We are proud to have been trusted by Penn to assist them in this challenging task. We look forward to a close and productive working relationship with Penn," says Ian Oxley, Validation and cGMP specialist for the IntegraLab team.

IBA is exhibiting at booth number #709 at the Society for Nuclear Medicine (SNM) Annual Meeting 2012 from 9-13 June in Miami, Florida. For further information please visit: <u>http://www.iba-snm2012.com/booth-activities</u>

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#### About PENN

The Positron Emission Tomography (PET) Center and Cyclotron Facility at the University of Pennsylvania was one of the first in the United States. It was established in 1975 as a research facility for the study of human brain function. It continues to be a leading biomedical research institution with a large program in basic and clinical PET research with investigational studies in, neurology, psychiatry, cardiology, and oncology. More than 6,000 PET studies are performed by the PET Center each year.

#### About IBA

IBA (Ion Beam Applications S.A.), is a cancer diagnostics and treatment company and the worldwide technology leader in the field of proton therapy. The Company's expertise lies in the development of next generation proton therapy technologies and radiopharmaceuticals that provide oncology care providers with premium quality services and equipment including IBA's leading fully integrated IntegraLab® system.

Headquartered in Belgium and employing more than 1200 people worldwide, IBA currently has installed systems across Europe and the US and is expanding into emerging markets. The Company is focused on building sustainable global growth for investors and provides high quality services and products for oncology specialists and cancer patients.

IBA is listed on the pan-European stock exchange EURONEXT. (IBA: Reuters IBAB.BR and Bloomberg IBAB.BB) and more information can be found at: <u>www.iba-worldwide.com</u>

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