

BIONT

Organisation Legal Name **BIONT, a.s.**
(Trade Register)

(Derived from: Bratislava ION Technologies)

Type Joint stock company

Stock Holders Ministry of Education of the Slovak Republic
Ministry of Health Care of the Slovak Republic
Ministry of Economy of the Slovak Republic
Ministry of Defence of the Slovak Republic
Slovak Office of Standards, Metrology and Testing

Basic stock 1.056 billion SKK (about 32 mil. EUR)

Chairman of the Board of
Directors and Director General Assoc. Prof. Peter KOVÁČ, Ph.D.
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Headquarter GPS B=48°10'04.72001", L=17°02'39.6388"

Established January 21st, 2005

Companies Register District Court Bratislava I, Sector Sa, File 3505/B

Organisation Reg. Number (ICO) 35 917 571

VAT Number SK 202 19 32 748

Bank Account 262 001 2634/1100 Tatra banka Bratislava

Bank Account (IBAN) SK09 1100 0000 0026 2001 2634

SWIFT (BIC) TATRSKBX

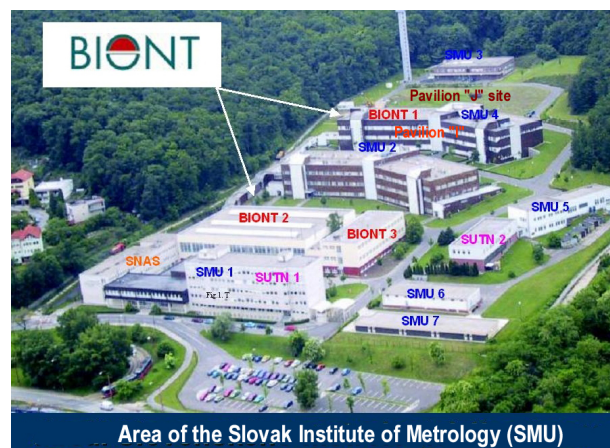
Average number of employees 50

BACKGROUND

BIONT is linked to the „Cyclotron Centre of the Slovak Republic”, which is a project carried out by the Slovak Office of Standards, Metrology and Testing since 1997, with the aim to establish a multi-purpose scientific centre and production facility ensuring

- the basic and applied research in radiochemistry, physics, biology and medicine,
- production of radionuclides and radiopharmaceuticals,
- other application of accelerator technologies in medicine, materials science and industry.

The Cyclotron Centre of the Slovak Republic (CC SR) was projected earliest as a cyclotron laboratory and later as a system of two accelerators. Both were decided to be allocated in their dedicated buildings of the area of the Slovak Institute of Metrology (SMU), located in the district Bratislava - Karlova Ves. A reconstruction of pavilion "I" and a new construction of pavilion "J" were conceived.



Pavilion "I", where also the Centre for Ionizing Radiation of SMU is dislocated, was partially reconstructed for operation of a commercial **cyclotron, Cyclone 18/9** (IBA, Belgium). Clean rooms for preparation of PET radionuclides were designed for commercial production of short-lived positron emitters in vicinity of a medical diagnostics unit.

Pavilion "J" is designed for dislocation of the proton, deuteron, helion and heavy ions **accelerator DC-72** constructed in the Joint Institute of Nuclear Research (JINR) in Dubna (Russian Federation). The experimental devices for physics, material science and heavy ion applications are envisaged at three beam channels, two channels are planned for radiation therapy practice and research, and three channels are designed for radionuclides production.

The whole project is launched and revised by Slovak Government's resolutions Nr.434/1996, Nr.659/1999, Nr.660/1999, Nr. 865/2000, Nr.407/2001, Nr.875/2002, Nr. 1003/2004, Nr. 1195/2004, Nr. 970/2007, Nr. 1105/2007, Nr. 242/2008, and Nr. 322/2008.

The state owned **Joint Stock Company BIONT, A.S.** has been established from the finished parts of the project since January 21st 2005, according to the Slovak Government's resolutions Nr.1003/2004 and Nr.1195/2004 from October 2004 and December 2004 respectively. According to the last resolution Nr. 322/2008 from May 21st, 2008, 95% of shares of the company should be transferred to the Ministry of Education of the Slovak Republic and the rest to the Slovak Office of Standards, Metrology and Testing.

CORPORATION

The reconstructed buildings “D”, “E” and “I” in the area of the Slovak Metrological Institute and building “C” in the hospital area Bratislava-Kramáre became the property of company at its establishment in 2005:



Object "I" - BIONT headquarter



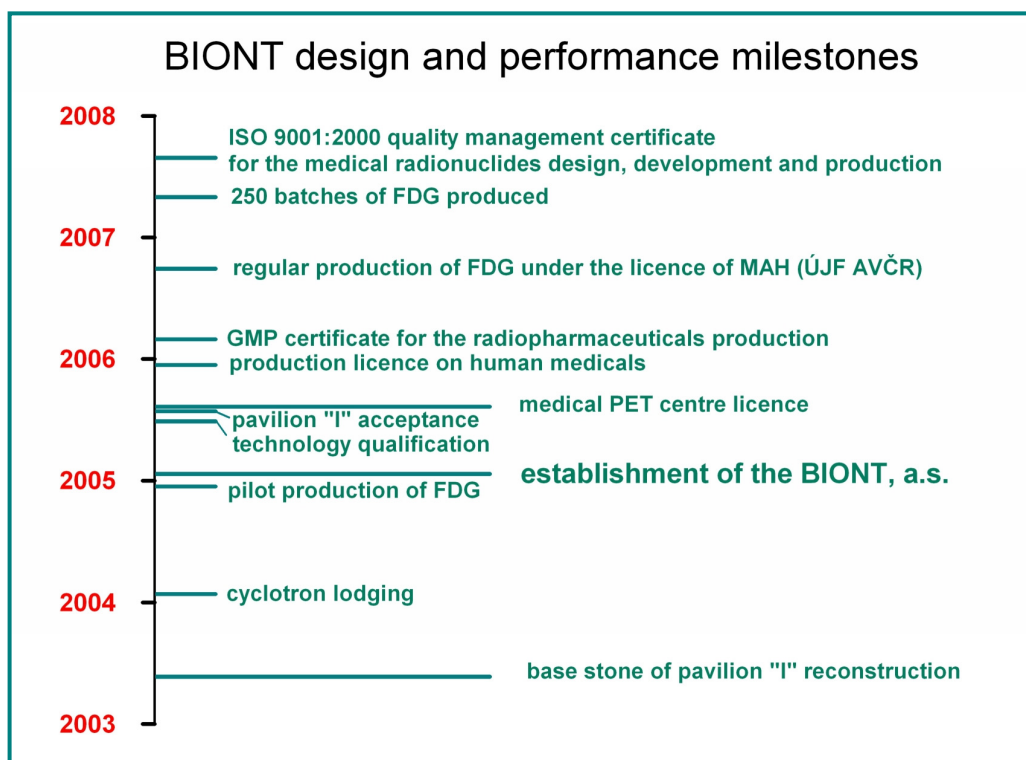
Objects "D" (workshops) and "E" (offices, stores)



Object "C" - guest house

The core staff of emerging company BIONT was primarily recruited from the faculty and students of the Slovak Technical University and Comenius University in Bratislava under full-time and part-time job contracts with the Slovak Office of Standards, Metrology and Testing. Originated, it was professionally prepared and trained at the home and foreign institutions till the end of 2004. During the years 1994-2004 the International Atomic Energy Agency provided, within the frame of technical co-operation program SLR/2/002, and except the basic laboratory and production equipment and expertise, the most valuable help in the implantation of necessary knowledge. There was lack of experience in the field of radionuclide and radiopharmaceuticals production, and Slovak scientists were getting necessary know-how and experience of best practice at European cyclotron and radiopharmaceutical facilities (Berlin, Bologna, Copenhagen, Darmstadt, Debrecen, Dresden, Dubna, Geneva, Gröningen, Helsinki, Jülich, Jyväskylä, Klagenfurt, Karlsruhe, Louvain-la-Neuve, Manchester, Moscow, Prague, Saint-Genis-Pouille, Turku and Uppsala).

Thanks to these preparations, the period from the technical accomplishing of technology till its performance, operational qualification and licensing was squeezed to less than one year:



At present, in the BIONT's main building (pavilion "I") the essential company laboratories and departments are located, as the

- **nuclear medicine PET centre** (Head: Pavol Povinec, M.D., Ph.D.),
- **medical radionuclides and radiopharmaceuticals research and development unit** (Project Manager: Prof. Pavol Rajec, DrSc.),
- **department of radiopharmaceuticals production** (Head: Mgr. Erzsébet Losonczi Pataky),
- **department of radiopharmaceuticals quality control** (Head: Dipl. Ing. Zoltán Kassai, Ph.D.),
- **department of microPET** (Head: Svorad Štolc, M.D., DrSc.),
- **department of nanotechnologies** (Head: Assoc.Prof. Vladimír Gašparík, Ph.D.), and
- **department of radiation safety** (Head: RNDr. Daniel Baček).

The technology for radionuclides production involves:

- [^{18}F]FDG (routine production by TRACERlab MX_{FDG} module, 50-80 GBq per run),
- [^{18}F]DOPA and [^{11}C]raclopride - operation qualification synthesis,
- [^{11}C]CH₃I / [^{11}C]methionine - validation synthesis,

and also targetry for [^{15}O]O₂ and [^{13}N]NH₃ production is available (till now, without radiochemical modules). A solid target COSTIS and a TERIMO separation module are qualified for production of the positron emitting radionuclides complementary to SPECT radionuclides, e.g. ^{124}I (together with ^{123}I) and $^{94\text{m}}\text{Tc}$.

The production of [^{18}F]FDG radiopharmaceutical for cancer diagnostics was launched commercially since February 2006 under the license of the Nuclear Physics Institute of the Academy of Sciences of the Czech Republic (Řež near Prague) as the Marketing Authorization Holder, with product distribution both in the Slovak and Czech republics. To the end of May 2008, production units ensured 987 commercial deliveries of [^{18}F]FDG at average activity 4.3 GBq at the customer reference time. Now the company is in a final stage of the Decentralized Procedure of the own marketing authorization of "biontFDG" by Common Technical Document according to ICH 2000, with possible extension to Mutual Recognition Process in EU countries



Cyclotron



Clean rooms



Quality control



Development and research

Specifically, due to unexpected opposition from the public, and also because of the neighborhood of metrological radiation laboratories, a thorough **radiation protection design** and sophisticated **radiation monitoring system** were established to guarantee a dose less than 1% of natural radiation background from the BIONT facilities to the individuals from public in the area surroundings.

All production laboratories were built to fulfill the current European Union Good Manufacturing Practice (GMP) guidelines for human drug production, regulations for radiation safety, health care, and environmental protection:

- Slovak Republic Radiation Protection Act 470/2000.
- Slovak Republic Health Care Acts 272/1994 and 576/2004.
- Slovak Republic Drug Control Acts 140/1998 and 663/2004.
- EC Directives 99/11, 99/12, 2001/83, 2003/94, and 2004/27.
- ICH Q7A Guidance for Good Manufacturing Practice.
- GAMP4 Guide for Validation of Automated Systems, ISPE 2000.

As an umbrella for all these regulations, a **quality management system** according to ISO 9001:2000 has been created since 2005 (Quality Manager - Prof. Fedor Macášek, PhD, DrSc.). In August 2007, the Lloyd's Register Quality Assurance (Lloyd's Register EMEA, Prague Office) approved it as applicable to the design, development and production of medical radionuclides and radiopharmaceuticals.



Nuclear medicine department – PET Centre is equipped with a PET/CT camera “Discovery LS”, the first PET/CT system designed by GE in 2001 with an integrated compact gantry for fusion imaging, and a **SPECT/CT coincidence camera** “*Millennium Hawk Eye*” (GE). The company owns also the PET tomograph „*ECAT EXACT HR+*” (Siemens) operated at the St. Elisabeth Institute of Oncology Ltd. (Bratislava), and another *Millennium Hawk Eye* camera the Central Military Hospital (Ružomberok, North Slovakia) respectively. For the pre-clinical studies a laboratory equipped with a **microPET** „*eXplore Vista Pre-Clinical PET Scanner*” (GE) for small laboratory animals has been created in cooperation with the Institute of Experimental Endocrinology of the Slovak Academy of Sciences (Bratislava).



SPECT /CT coincidence camera *Millennium Hawk Eye*



PET /CT tomograph *Discovery LS*



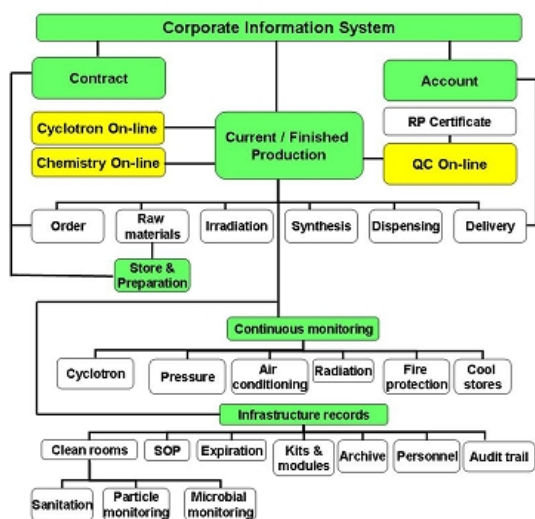
microPET *eXplore Vista*

In the PET centre of BIONT company, 2930 patients from Slovakia and abroad have been investigated by PET/CT tomograph and 1380 patients by SPECT/CT camera to the end of May 2008.

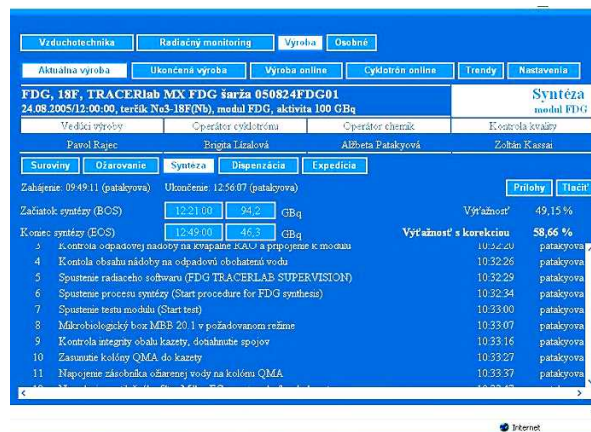
Corporal information system was tailor-made for the company's global needs by information technologies specialists (Leader - Dipl.Ing. Jozef Staňo, Ph.D.) HTTP server uses Apache-AdvancedExtranetServer 2.0.4, and the operation system works under Mandrake Linux 9.2. The requirements of 21 CFR Part 11 and GAMP4 were implanted in. It ensures electronic documentation using the encryption algorithms MD5-SHA1 for the on-line processes control and verification not only according to GMP but to the total quality management rules, starting

from input materials order till the issues of pharmaceutical analytical certificates and other delivery documents.

The information system minimizes a subject influence on records, keeping the hard copies down to the minimum required by the GMP inspection and customers needs.



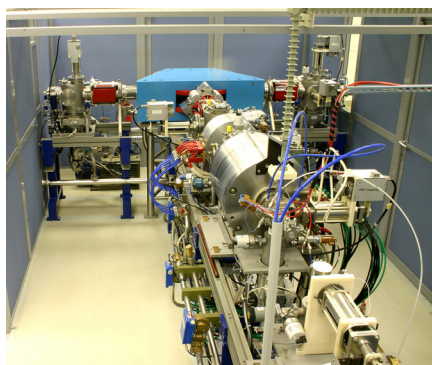
Corporate information system



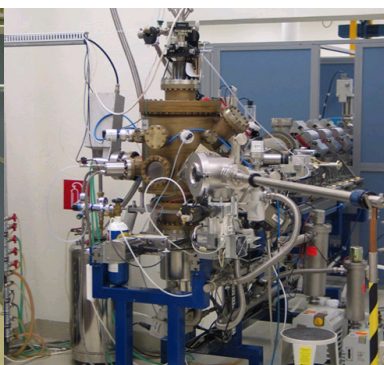
On-line FDG production control board

Department of nanotechnologies comprises several laboratories equipped as follows:

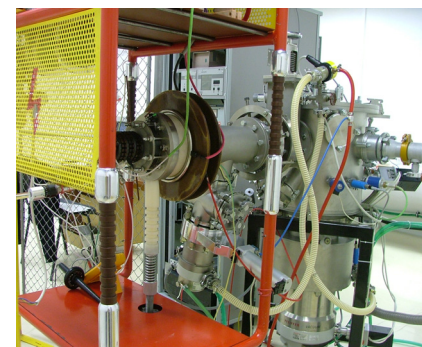
- **Electron cyclotron resonance (ECR) heavy ion source DECRIS-2M** (Joint Institute of Nuclear Research, Dubna) with maximum extraction voltage of 25 kV and ${}^7\text{Li}^{2+}$ - ${}^{132}\text{Xe}^{18+}$ beam transport system with scanning to 120x120 mm² area
- **UHV target chamber**, with a rotary sample and sample temperature variable from -196°C to +1100°C, in-situ sputter-cleaning of the sample surface, and in-situ thin films deposition
- **Spectrometer of Auger electrons** with electron beams of 20 μm diameter and energy 3 keV. The absolute sensitivity 10⁻¹⁴ g, relative sensitivity 10⁻³ %.
- **Scanning probe microscope (SPM) Solver P47** for high-resolution studies scanning tunneling microscopy, scanning tunneling spectroscopy, atomic force microscopy, phase imaging, magnetic force microscopy, electrostatic force microscopy, scanning capacitance microscopy, and nano-lithography).
- **Mask Lifetime Test-bench (MLT)** adapted for development of ion sources and testing of the ion beam induced erosion. It comprises:
 - Ion injector system with exchangeable ion sources (duoplasmatron, RF, PIG)
 - Target chamber with 4 motion precise goniometer and beam characterization system



ECR ion source

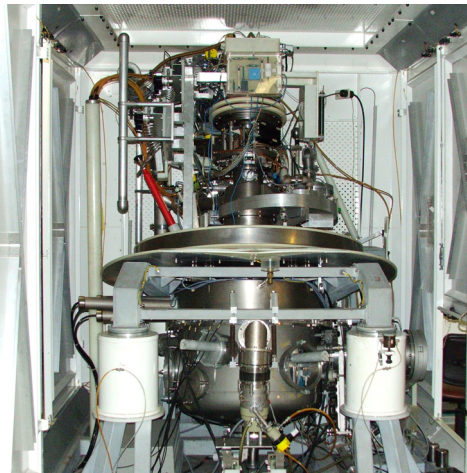


UHV target chamber

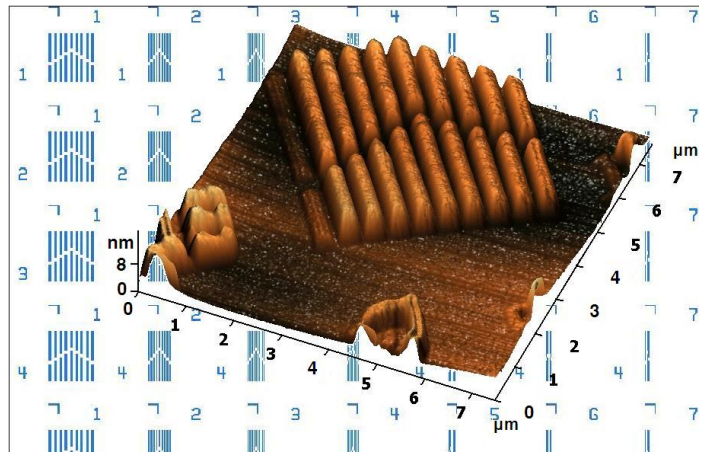


Mask Lifetime Test-Bench

- **Ion projector** was developed by Ionen Mikrofabrikations Systeme, GmbH, Vienna, for Institut für Silizium Technology, Fraunhofer Gesellschaft (ISIT FhG), Germany. After several years of successful operation it was in March 2008 moved to BIONT.



Ion projector



Test mask layout

The homogeneous 10-75 keV noble gas ion beam is directed to a stencil mask prepared by a conventional lithography. After passing the mask the ion beam is split to several microbeams shaped according to the features on the mask, wafer size x-y movement 4 inch, exposure field of wafer (density up to $2 \times 10^{12} \text{ Ar}^+ \text{ cm}^{-2}$) is $1 \times 2 \text{ mm}^2$ and resolution 20 nm.

The company research projects and cooperation with other institutions include:

- Charged Particles Nanotech EC 6th Framework Program, Integrated Project IP-515803-2 CHARPAN.
- Multifunctional oxide layers - Grant APVT-20-011804.
- Development of superhard materials based on carbide and nitride layers, accenting the diamond and cubic boron nitride - Grant APVT-20-0034404.
- Superconductors for future technologies - Grant APVT-51-016604.
- Preparation of the submicro- and nanometric structures using sophisticated lithographic methods - Grant AV 4/0037/07.
- Neuroprotective action of new pyridoinol antioxidants - Grant APVV-51-01705.
- Epigenetic risk factors of cerebral infarct - Grant APVV-058606.

Basic economical data of the company

	mil.SKK \approx 33 k€		
	2005	2006	2007
Turnover	18	101	136
Net Performance	39	93	151
Added Value	-5	43	69
EBIDTA *	-23 **	18	32

* Earning before interest, taxes, depreciation and amortization

** Planned value: 45 mil.SKK

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