

iPETpro[®]

Nobody knows everything,

but everyone wants to know everything;

everyone wants to be the best,

but only someone makes the best decisions...

information system for PET Labs

What you need to know

What you definitely know is that Good Manufacturing Practice (GMP) in radiopharmaceuticals production is connected with a comprehensive control and documentation system, to safely store and adequately handle a lot of data in a rather short time.

Get rid of enormous paper work! We are offering you a professional tailor-made solution!

Integrated **PET** Radiopharmaceuticals **Production System** – **iPETpro®** is robust, complex, cost-effective and an open information system for PET radiopharmaceuticals production and quality control labs. It is the first and only system in the world for PET radiopharmaceuticals production laboratories which is open for further development by the company's own specialised staff under special license and warranties conditions. The system has a fully internationalised, themed and user-friendly web-based interface, compatible with all major internet browsers. Optional custom-made modules can also run Android OS based smartphones and tablets. The main advantages of our open **iPETpro®** project are high variability and unlimited possibilities to improve all functions based on customer's requirements. During development of **iPETpro®** we took into consideration the project lifecycle and software validation within the conditions of ISPE GAMP5®. The software instructions are user-friendly and can be made available in English or Russian on your request.

The software company minus2, s.r.o. was founded in 2006 by IT and software engineers, who were part of the group who first developed PET center in Slovakia known as BIONT, a.s. Since 2005 until now, we have improved this very specific information system, to be a foundation for the whole PET radiopharmaceuticals production process from planning, checking resources flows (materials, personals), preparing phases, cyclotron irradiation, chemical synthesizes, radiopharmaceuticals dispensation, quality control checking and expedition. Functions and logical workflows are based on real-life production needs and are designed to help staff to rapidly improve their performance. To avoid operator's mistakes in standard operating procedures (SOP), the system requires confirmation of predefined steps in accordance with validated SOP. Direct communication of software modules with equipment such as cyclotrons, hot cells, synthesis modules, dispensation modules and subsystems like radiation protection, air-conditioning, company ERP allows the system to be devoid of human errors over a high range of data handling procedures. Interconnectivity with equipment and subsystems have further advantage in very practical, useful and easy configured E-mail and SMS notifications. The notification module can monitor all parameters integrated into the system and inform operators and other staff about the state of the facility 24-hours a day. This enables us to comfortably monitor online the vacuum conditions in the cyclotron chamber, humidity or sub pressure in the production clean room areas and much more. Reporting functions automatically create PDF documents of certificates, analytical, production, ADR reports, vials, cover labels and other prescribed documentation. The system **iPETpro**[®] also features clean rooms, devices and maintenance scheduling and logging of other systems. The module for Quality Control Lab combines the managing and logging of physical quantities from analytical methods and performs customised calculations over them. With the help of the audit trail function, the system monitors all user's activities to simplify reverse inspection. User's rights apply on module and function levels.

Logical Scheme **iPETpro**[®]

| | | | | | |
|----------------------------------------|-----------|-----------------------------------------------------------------------|---------------------|-------------------------|--------------------------------------------------------|
| Company ERP System or built-in planner | Cyclotron | Synthesis & Dispensing Modules Synthesis & Dispensing Hotcells | Aircondition System | Radiation Safety System | Custom Systems can be whatever on customer site |
|----------------------------------------|-----------|-----------------------------------------------------------------------|---------------------|-------------------------|--------------------------------------------------------|



iPETpro[®]

| | | | | | |
|-----------------------------|-----------------------------------------|------------------------------|---------------------------------------------------|-------------------------------------------------------------------|----------------------------------|
| Planning | Preparing materials, weighting | Irradiation process handling | Synthesis process handling | Dispensing process handling | Quality Control process handling |
| Expedition process handling | PDF reporting, prescribed docs creating | Historical data trends | Real-time data watchdog Email&SMS notification | Clean rooms, devices and systems maintenance scheduling & logging | Audit trail |

Who will profit

The answer is in the following ten questions:

- 1 Do you want to see the actions and status of the running process beginning from the preparation of materials, production and quality control, up to the product release from one centralised site? 
- 2 Do you want to be sure that operators meet all requirements according to standard operation procedures whilst doing their job? 
- 3 Do you want to avoid human based errors during rewriting production data and to follow their calculations? 
- 4 Do you want your employers to be stress-free when filling in complicated forms for certificates, production documentation, ADR reports, etc. ? 
- 5 Do you want to be able to look anytime at the historical data of physical parameters during the production process? 
- 6 Do you want to be notified by E-mail or SMS 24-hours a day as the changes of physical parameters occur, e.g. if the vacuum in the cyclotron chamber or the clean rooms parameters are within its limits? 
- 7 Do you want to have central storage organised of electronic batch records, production or quality control lab documentation? 
- 8 Do you want to be worry-free about reporting any discrepancies during the production cycle to a competent person and stay informed about the outcome ? 
- 9 Do you want to be a respectable producer, who would never find themselves in an uncomfortable situation with the regional institute for drug control, which requires the relevant documentation for very old productions? 
- 10 Do you want to have a modern information system which you can improve also by specialised IT personal in your company? 

Is **iPETpro**[®] profit for your business and PET Laboratory?

You know the answer and we know how to do it.

Technologies

Application server

| | |
|---------------------------------------|-----------------------------------------------------------------------|
| Operational System | OS Linux (preferred), MS Windows Server Editions |
| Real-Time Data Acquisition Components | crondaemons, custom coded (PHP, C/C++), LabVIEW Development System |
| Database engine | MySQL |

Application web-based client

| | |
|-----------------------|------------------------------------------|
| Programming languages | PHP, HTML, JavaScript, jQuery components |
|-----------------------|------------------------------------------|

Application modules clients (optional custom's requirements)

Android OS smartphones and tablets

Connectors

ODBC database connectors (MySQL, MS SQL, ORACLE, ...)

XML, HTML Data Exchange

DDE Exchange

OPC technology

Import and parse files

Integrated Solutions

IBA Cyclotron Solutions

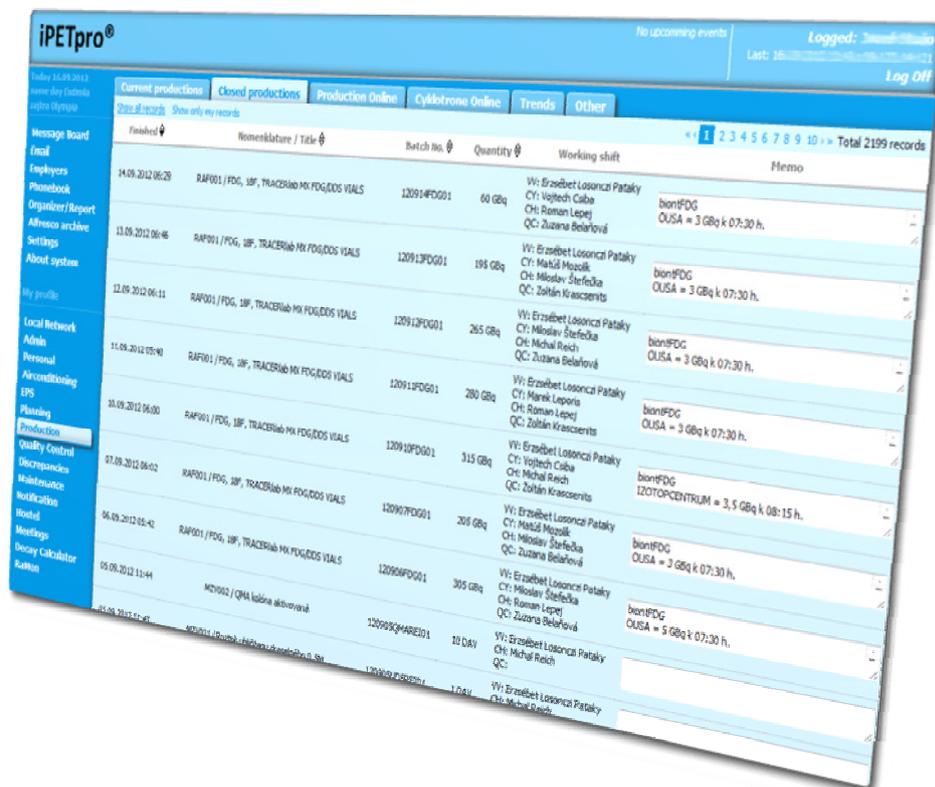
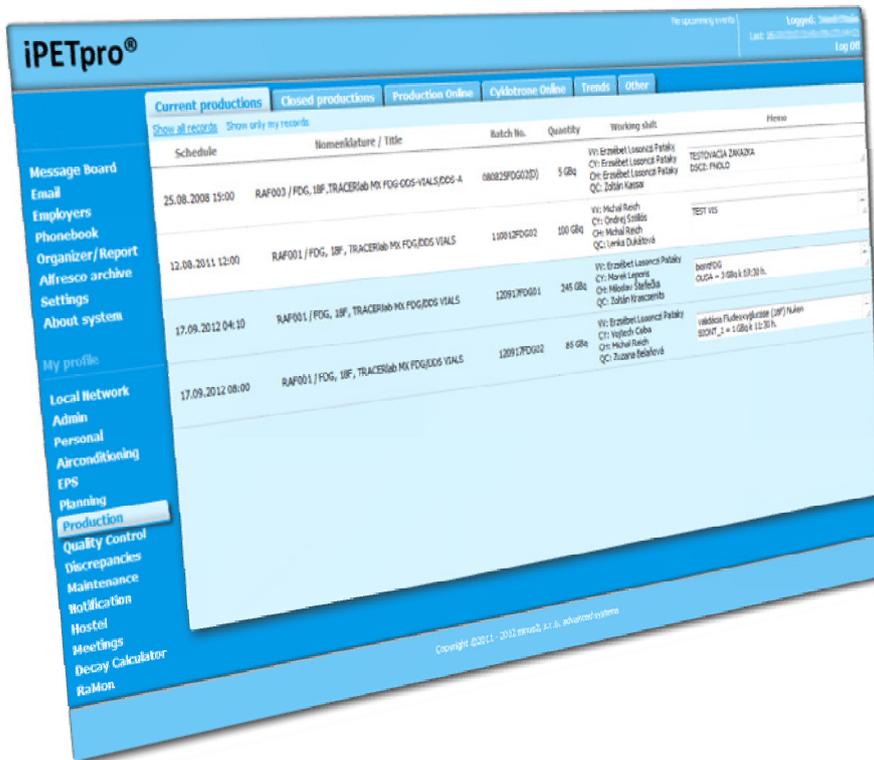
TEMA Sinergie

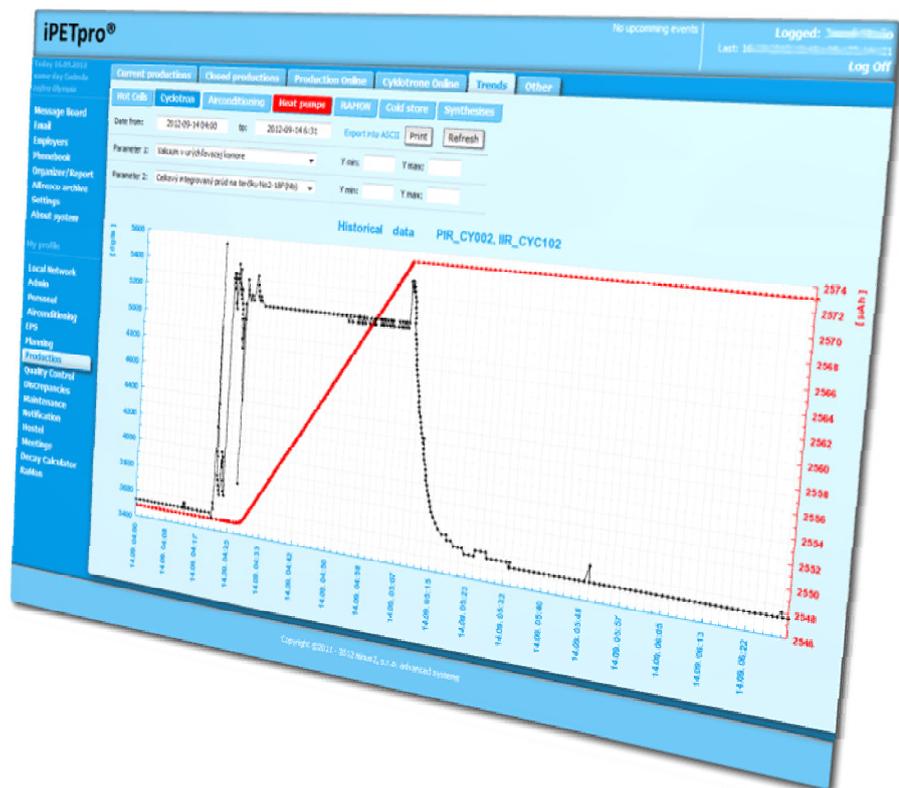
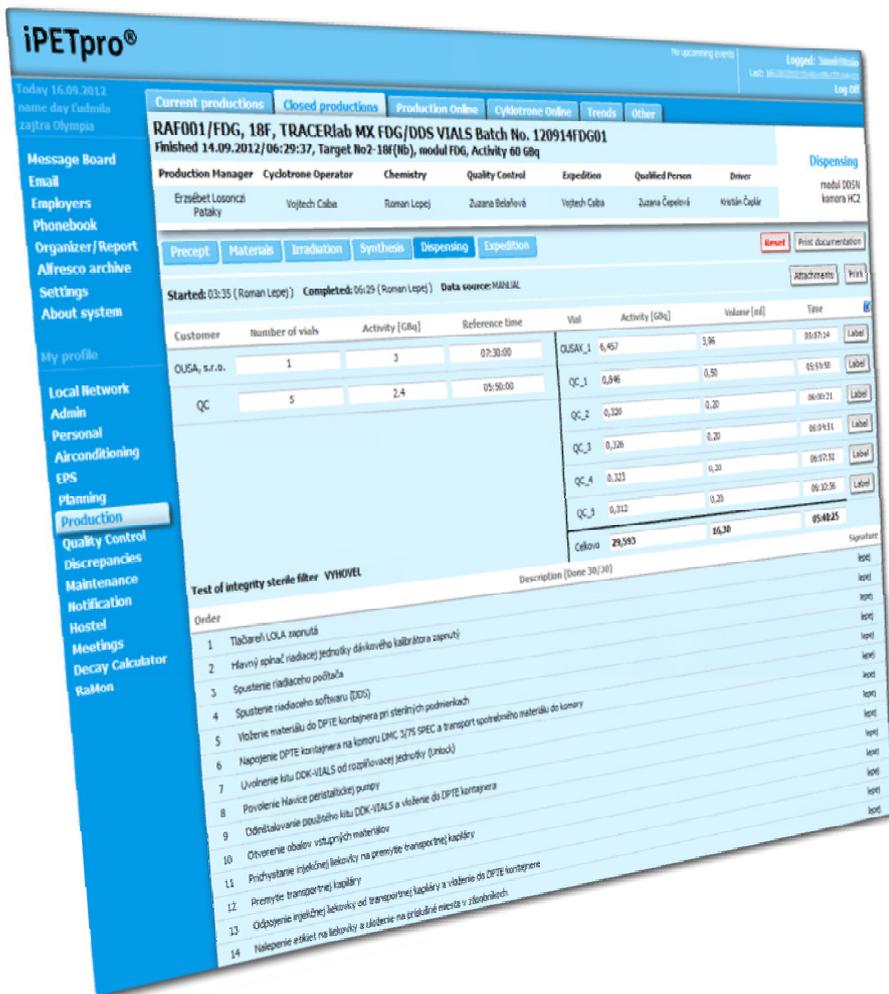
GE Healthcare

Johnson Controls

Canberra – Packard

Real Life implementation







minus2, s.r.o. | advanced systems
Rovniankova 16
851 02 Bratislava, Slovakia

<http://www.minus2.sk/iPETpro>