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GE Healthcare, a division of General Electric Company.

About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our “healthymagination” vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com

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GE Healthcare



TRACERcenter
One source. One complete solution.





What is TRACERcenter*?

One source. One complete solution.

GMP facilitation

Good Manufacturing Practice (GMP) principles are fundamental to everything we do at TRACERcenter. We apply these critical quality guidelines to your project from start to finish. TRACERcenter helps you develop and implement processes to fulfill your facility's GMP requirements.

We also offer you a comprehensive portfolio of GMP-compatible accessories and supplies that can help you stay in compliance for many years to come.

Technology expertise

TRACERcenter equips you with the right platform for your needs—a platform that combines innovative technologies with products from some of the world's finest radiopharmaceutical suppliers. You'll be positioned to take full advantage of advanced GE PETtrace* cyclotrons and high-yield chemistry synthesizers, and to integrate an exceptional combination of third-party hotcells, dispensers, quality control instrumentation and radiation-monitoring devices.

Local presence

No matter where, no matter when, uptime is critical. Our solution: TRACERcenter equipment service. It begins locally, so you'll always have someone on hand to meet your needs promptly. Our service support extends globally, to give you fast access to our unique, worldwide service infrastructure, through a single point of contact. It's comprehensive, including everything from service contracts and remote diagnostics to loaner equipment and upgrade paths.

Overall support

Setting up a state-of-the-art PET facility is admittedly a challenge. TRACERcenter covers all the angles from qualifying and validating your equipment, positioning you to manage all the requisite paperwork, training your staff and providing consulting services needed to make your program successful.

At TRACERcenter, we leave nothing to chance.

Working together

A successful PET tracer-production facility requires a major investment and a long-term commitment on your part, and on ours. At GE Healthcare, we're committed to helping the healthcare community understand disease, from the beginning. We're backing up this commitment with investments not only in research and development, but also in the infrastructure required to provide you with all the support you need.

GE Healthcare's TRACERcenter is a unique hub that integrates technology, scientific expertise and clinical know-how to help put you at the forefront of PET tracer production and imaging—anywhere in the world. Working closely with you to provide solutions customized specifically to your PET research site or clinical center, we can provide you with all the support you need throughout your program's lifetime.

The result? A tracer-production and imaging center you'll be free to operate with full confidence and complete peace of mind.



GMP • Good Manufacturing Practice

A complete and integrated **GMP** equipment, service and support platform for the production of PET tracers.

What is GMP?

Good Manufacturing Practice (GMP) is the part of a quality assurance system which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use.

Many countries have implemented pharmaceutical legislation, and issued guidelines on how to achieve compliance with the principles set out in their law. Whilst these guidelines are not mandatory to follow, adherence to the legislative principles is, and any deviation from the guidance must result in an equal or greater assurance of product quality.

To achieve GMP, critical processes need defining and documenting; equipment and facilities need validating; people need appropriate training, and the entire operation needs to be controlled under a robust Quality Management System (QMS).

With PET manufacturing proliferating worldwide, regulatory authorities are increasing both PET GMP requirements and their surveillance of the PET producers. Such inspections can be unannounced, therefore it is essential that you remain in a state of inspection readiness.

GMP compliant solutions stand behind each patient dose.

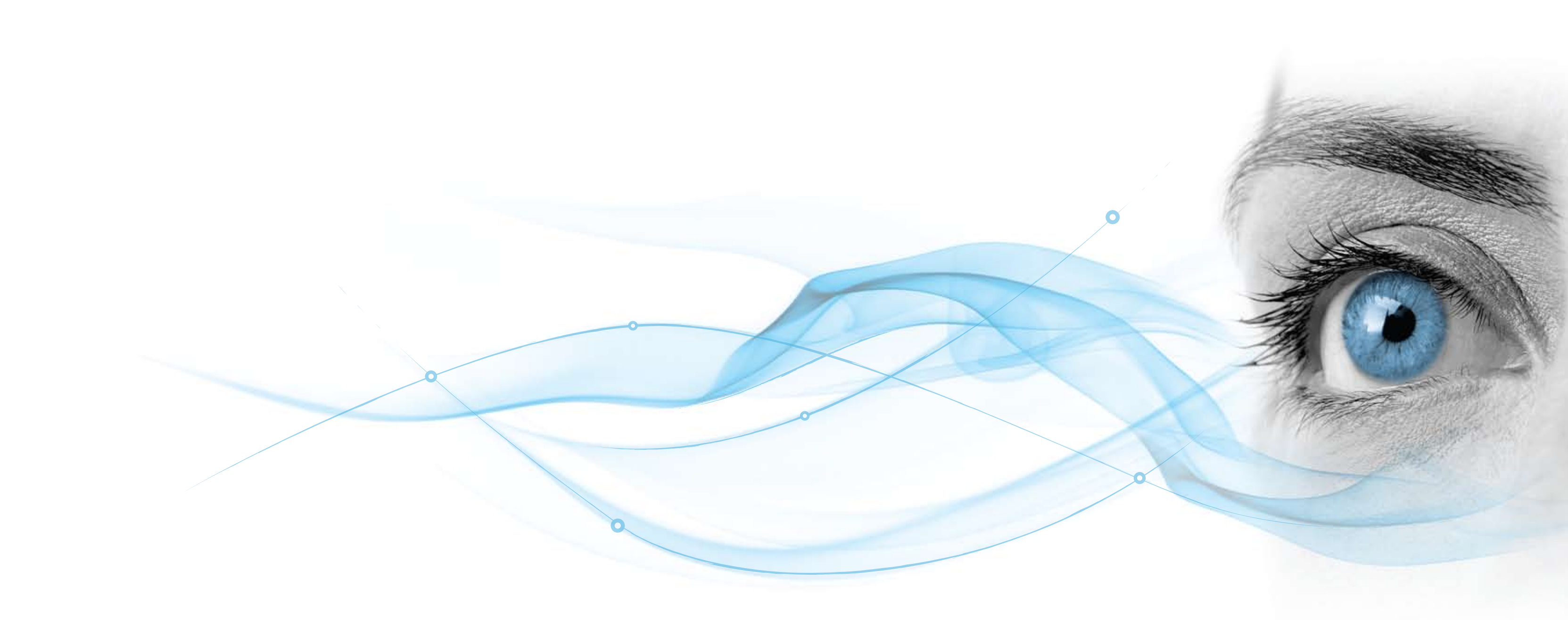
At GE Healthcare, adhering to GMP guidelines is mandatory for our own pharmaceutical business. This means we have the expertise and knowledge and are well positioned to help you create and implement a customized GMP project - a complete and integrated program designed to help enable you to meet the requirements of your local authorities.

At every stage of your project, through concept, design, build, documentation, training and the validation phases we can assist you with pharmaceutical specialists using proven pharmaceutical methodology to help you achieve a "GMP operationally ready" facility.

We also offer a complete line of GMP compliant equipment, accessories, supplies and a maintenance service to help you maintain your GMP status.

Our goal: helping you to create a compliant GMP operation to enhance the safety of your patients and meet the regulatory bodies expectation.

To our knowledge, no one else can provide you with such a comprehensive GMP solution.



Cutting-edge technology for the production of PET tracer doses.

Leveraging GE's 30 years as a leader in pioneering PET technology and cyclotrons, TRACERcenter is built on the solid foundation of proven GE equipment, including the remarkably reliable PETtrace family of cyclotrons and the innovative, automated FASTlab* PET radiochemistry platform.

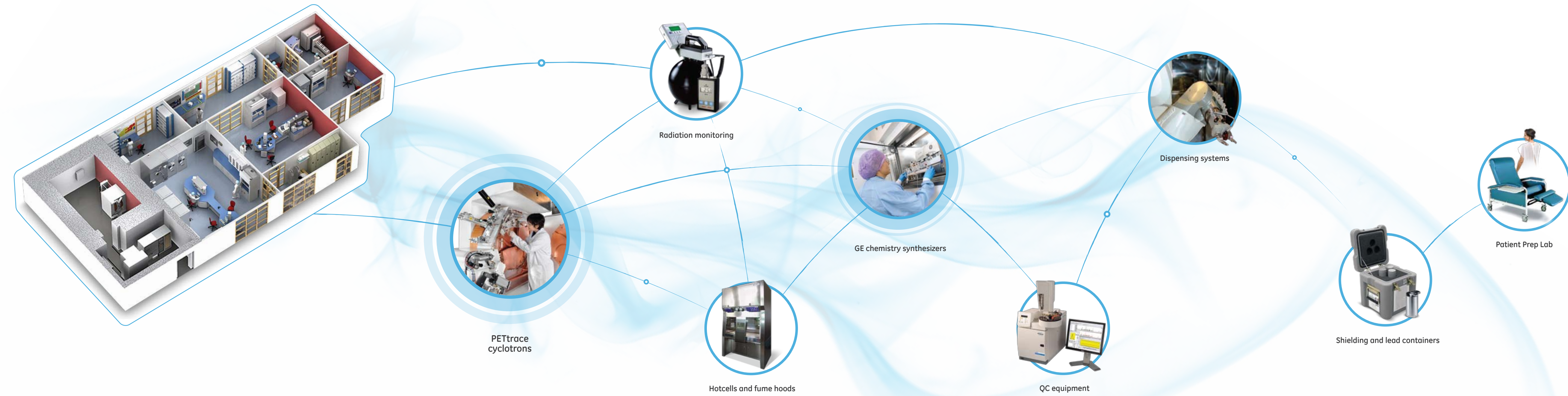
To this foundation we've added a carefully selected portfolio of exceptional production systems to meet your facility's needs precisely.

- PETtrace cyclotrons
- Hotcells and fume hoods
- GE chemistry synthesizers
- Dispensing systems
- QC equipment
- Radiation monitoring
- Shielding and lead containers
- Patient Prep Lab

Understanding disease begins in the production lab.

Producing PET tracers requires sophisticated laboratories with a wide range of advanced equipment. With TRACERcenter, we can help simplify the process by custom-designing a tracer-production facility to meet your specific needs.

The result: a solution that enables compliance with GMP guidelines, to help ensure that the radiotracers you produce are of the highest quality, offering maximum safety and efficacy.



Customize your PET center with our full support every step of the way.

There's nothing simple about establishing an in-house PET tracer-production and imaging center. It mandates expertise in disciplines from siting and pharmaceutical production to handling radioactive substances and licensing. It also mandates a major investment in multiple technologies.

Fortunately, TRACERcenter offers you all the expertise you need to help you establish a successful PET program; all the technology; and all the step-by-step support you want to bring your PET facility to life.

Among the tools:

Site-readiness and project - management support.

Carefully selected, qualified equipment with the requisite installation -and operation - qualification (IQ/OQ) protocols.

The documentation (Standard Operating Procedures, or SOP) needed to operate a facility under GMP guidelines.

On-site training, provided by GMP specialists, on performing GMP and FDG process qualification and validation (PQ/PV).

PETtrace cyclotrons

While our PETtrace cyclotron series sets the pace for production flexibility and reliability today, we are committed to providing you with an affordable upgrade path that helps protect your investment for many years to come.

Radiation monitoring

Radiation monitoring is critical to safeguarding personnel and patients in any PET facility. Count on TRACERcenter to provide you with all the necessary technology, equipment, and guidance to help you make yours the safest possible environment.

Hotcells and fume hoods

Your hotcell and fume hood requirements will depend in part on whether you're using the equipment for research, distribution or in-house production. That's why we offer a complete selection of products to meet your requirements while addressing both radioprotection safety and GMP guidelines. Every single one is compatible with, or configurable to, the full line of GE Healthcare chemistry synthesizers.

GE chemistry synthesizers

Whether your tracers start from ^{18}F -fluoride, ^{18}F - F_2 or ^{11}C -carbon dioxide or methane, you'll find just the right synthesizer for your production and research needs within the GE FASTlab and TRACERlab* families.

QC equipment

Designing a quality control lab is one of the most complicated tasks associated with tracer production, in part because it requires integrating many different technologies from many different vendors. But it's no problem for the experts at TRACERcenter - nor is adhering to regional regulatory guidelines along the way.

Dispensing systems

When it comes to dispensing and fractionating the patient dose, accuracy and efficiency are key. Whatever your preferences - vial or syringe delivery, automatic or manual operation - TRACERcenter will configure the best solution for your facility.

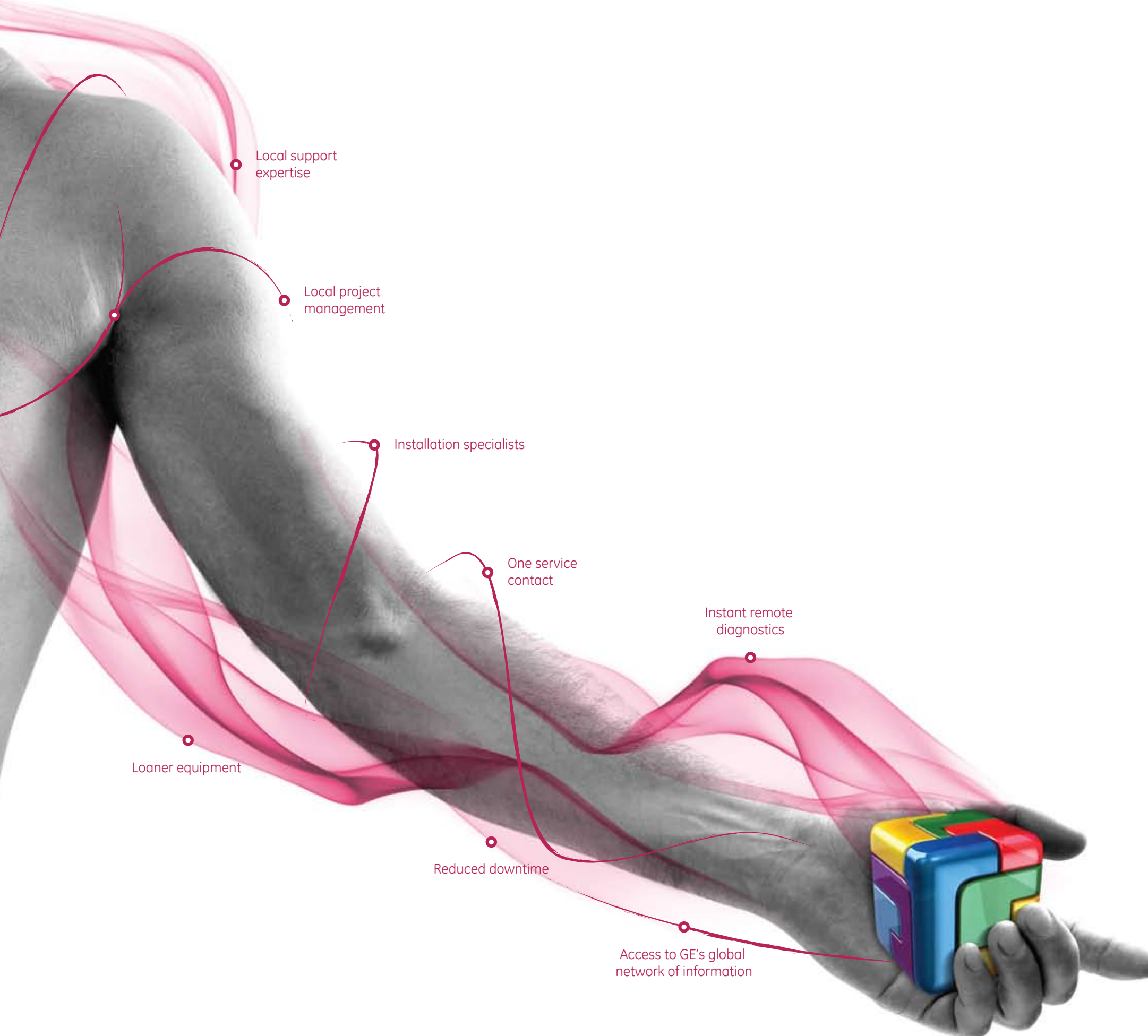
Shielding and lead containers

Reducing operator exposure to radioactive material is always a priority for a tracer-production facility. This is the reason TRACERcenter offers such a wide range of solutions, from shielded workbenches to lead containers.

Patient Prep Lab

Time is important in any imaging facility. But nowhere is it more important than in a PET center, where radiopharmaceuticals' short half-lives combine with tight scanner scheduling to make efficiency critical.

One excellent solution: the TRACERcenter Patient Prep Lab, designed and equipped to help you manage virtually any patient load with confidence and ease.



GE Healthcare offers
service coverage for
both GE and third-party
equipment.

One single point of contact for all your equipment.

There's much more to PET tracer production than hardware. It is a very equipment- and time-intensive process, however. If even one link in the chain goes down, your entire schedule is in jeopardy.

That's why your TRACERcenter has gone to great lengths to provide you with a complete service solution – a solution that offers comprehensive support for every component of your production line, from cyclotron through patient injection equipment.



"Since we acquired our GE PETtrace cyclotron in 2004, GE's experienced customer support team has been responsive and knowledgeable and able to resolve any issues, swiftly. In addition, GE's ability to quickly deliver requested service parts has provided us with maximum system availability in order to continue to serve our customers."

Will Lepeska
Wisconsin Medical Cyclotron LLC

"We were looking for a solid partner with a vision... fitting our ambition. GE Healthcare built a team of professionals around us, allowing us to be operational within one year after breaking ground."

Mr. Mehmet CAN
CAN Radyofarmasotik

"All the upgrades and enhancements released have been successfully retrofitted to our cyclotron installed more than 8 years ago. We've been working together with GE on cyclotron feature enhancements and great communication lines with the development engineers have enabled us to achieve improved performance."

It has been very satisfying to see issues and recommendations raised as part of the evaluation being promptly addressed. The collaborations have been very beneficial and satisfying for RPAH and allowed RPAH to take maximum advantage of the very substantial capabilities of the cyclotron and radiochemistry systems".

Stefan Eberl
Royal Prince Alfred Hospital

Anytime, anywhere.

Extended service

The TRACERcenter commitment continues well beyond the first dose you administer to a patient.

We offer extended service contracts post-warranty, contracts that include preventive maintenance for all the equipment we install, to help ensure you of maximum uptime year after year.

Uptime assurance

Our local and globally supported field engineers are reinforced by our InSite* remote diagnostic service to make sure you are back up and producing PET tracers as quickly as possible. The TRACERcenter loaner parts program also allows you to continue producing tracers in your facility should any of your third-party equipment require servicing.

Worldwide coverage and service support

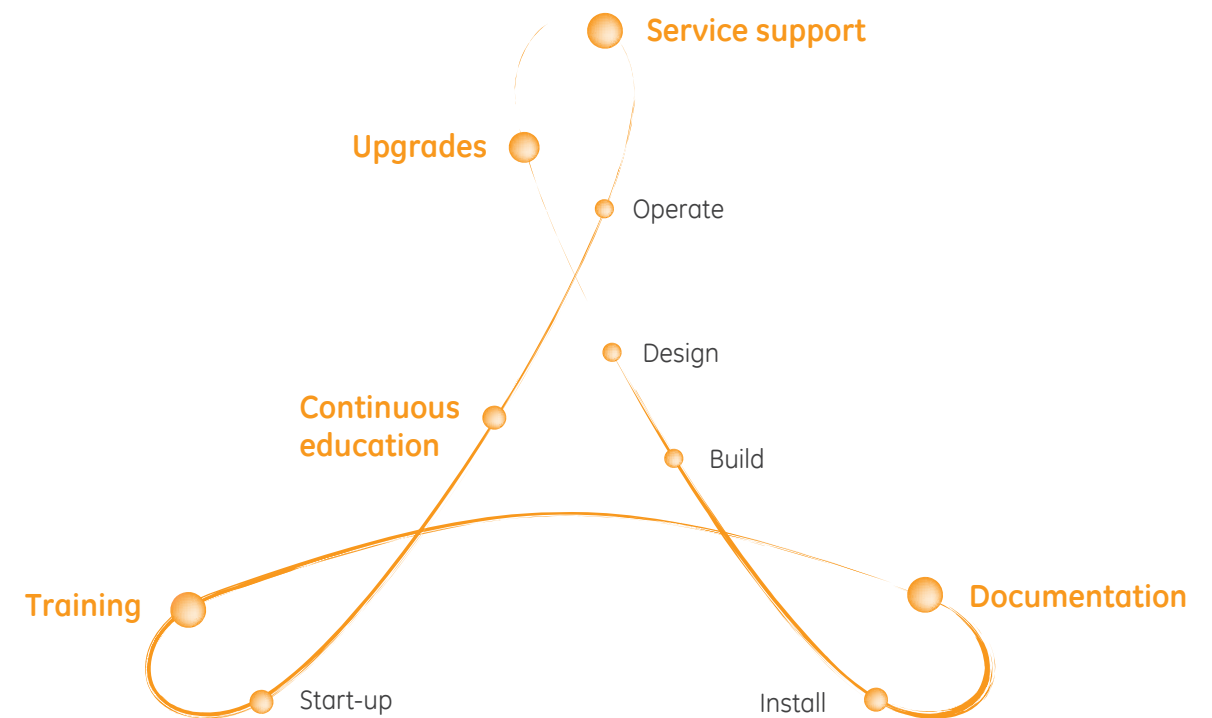
With complete TRACERcenter facilities located around the globe, and an extensive installed base of PET cyclotrons, chemistry synthesizers and PET/CT imaging systems, GE Healthcare is well suited to help you build a successful PET program.



Overall support throughout the process.

Through the entire process from site design through start up and beyond day to day operations, TRACERcenter offers you support through the lifetime of your PET tracer production facility.

This includes documentation assistance, training programs, continuous education, equipment upgrade paths and service support you can count on.



Documentation

While each program varies based on user needs, there are common components – including a custom-tailored Quality Assurance Program, SOPs, and QMS, while adhering to all relevant GMP guidelines. Also included are facility-wide qualification and validation documentation. We even assist you in your application for the required operational license.

Training

In addition to leading equipment technology and in depth guided processes and procedures, TRACERcenter delivers customized, hands-on training solutions for your entire staff. We make sure they understand the big picture, and the role that each system and process play in producing top-quality tracers and how GMP compliance fits into each step. Your facility's staff can be confident in carrying out their personal responsibilities, to help optimize compliant production from the start.

Continuous education

The field of molecular imaging, with its equipment, procedures, and regulatory guidance, is constantly developing and changing. TRACERcenter makes ongoing educational opportunities available to your team as new technologies – and your facility's regulatory requirements – continue to evolve.

Service support

You expect fast, local service support. That's precisely what TRACERcenter delivers, via teams of highly trained field engineers who are reinforced by our InSite remote diagnostic service. They are also backed by a worldwide service infrastructure to get any needed parts to your door as quickly as possible – and by a innovative loaner parts program to keep your facility up and running until the new parts can be installed.

Upgrades

For decades, GE Healthcare has been committed to providing customers across product lines with investment protection, primarily through cost-efficient hardware and software upgrades. GE TRACERcenter applies this same strategy to tracer production. Our goal is to help your facility stay affordably at the forefront of technology for years to come, in the process enabling return on your investment.



Working together.

We share the same ultimate goal: providing all the advantages of PET imaging to every patient who stands to benefit from this extraordinary technology.

By working together we can help design and validate a facility that meets your needs, train your staff in the operations of the equipment, and tailor Quality Management Systems and Quality Documentations for your process.

Our turn key solution involves a collaboration with you to create a functioning GMP operation, not a building with equipment installed. Together with TRACERcenter, you can streamline this process and provide patients with access to the benefits of PET imaging.

Perhaps most important, TRACERcenter can do all this with GMP compliance in mind, while providing you with a single point of contact to keep it all operating as flawlessly as possible, from the start.

A comprehensive solution to address your need to rein in costs while enhancing both the quality of healthcare delivery and patient access.

For more information on GE Healthcare's TRACERcenter and our end-to-end solutions, please visit us at: www.gehealthcare.com/tracercenter



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