

making a difference



# HOW WE SUPPORT YOU

**VACUETTE®**

**Blood Collection System**

Verification and Implementation Plan  
for Hospitals and Laboratories

  
**greiner**  
BIO-ONE

The easy way to optimal blood sample quality and to a safe blood collection technique is the introduction of the VACUETTE® blood collection system.



## PHASES OF IMPLEMENTATION

Greiner Bio-One has a wealth of experience in implementing conversions and demonstrates how planning and implementation can take place concurrently utilising

members of the Greiner Bio-One training team. Greiner Bio-One will be providing a suitable implementation timeline that includes the following 5 basic phases and steps:

### 01. PREPARATION PHASE

- Identification of Customer Needs and Compatibility Check
- Laboratory Checks
- Tube Guides
- Stock Levels, Changeover Timelines and Ordering Details
- Communication - Informing End Users

### 02. ESTABLISH IMPLEMENTATION PLAN

- Planning Implementation Days
- Planning Post Implementation Days

### 03. TRAINING

- Planning Training Sessions
- Training Material and Support

### 04. IMPLEMENTATION

### 05. FOLLOW UP

- Post Implementation Days
- Post Implementation Training and Support

# 01. PREPARATION PHASE

## IDENTIFICATION OF CUSTOMER NEEDS AND COMPATIBILITY CHECK

The target of this section is to:

Check components of the VACUETTE® Blood Collection System (e.g. safety holder/needle, safety blood collection set, holder and tube).

Check laboratory equipment: e.g. analysers, centrifuges.

Check instrumentation compatibility for the VACUETTE® Blood Collection System. If there is no information about compatibility of the analyser available on site, please contact the Technical Services in Austria (faq.pa@gbo.com) for support.

## LABORATORY CHECKS

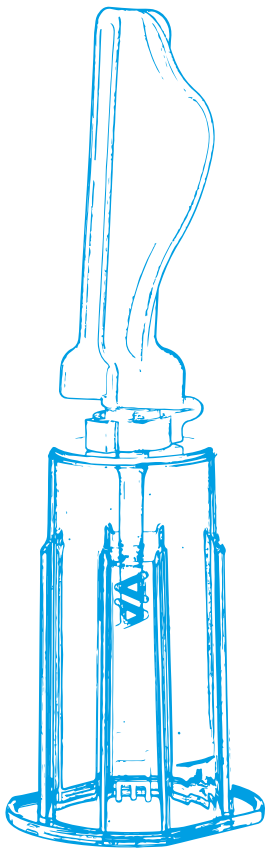
Once the laboratory has decided exactly which VACUETTE® Blood Collection Tubes they wish to use, a check would be done to ensure full compatibility of the chosen tubes. This check would assess analyser adaptations or modifications, racking systems, centrifuges, transport containers and any other equipment used during the analytical process.

If required, the laboratory should have discussions with the manufacturers of analysers to ensure full compatibility. This would determine whether a "Day One" start or "Roll-out" conversion would be most suitable. In either case, the following process would be initiated but for a "Day One" conversion, all stock will be delivered to all end users prior to the conversion day.

## TUBE GUIDES

Tube Guide charts in the Order of Draw can be provided when necessary, to ensure that samples are being drawn

in the correct order. Specific training and information literature are also available if required.



## STOCK LEVELS, CHANGE OVER TIMELINES AND ORDERING DETAILS

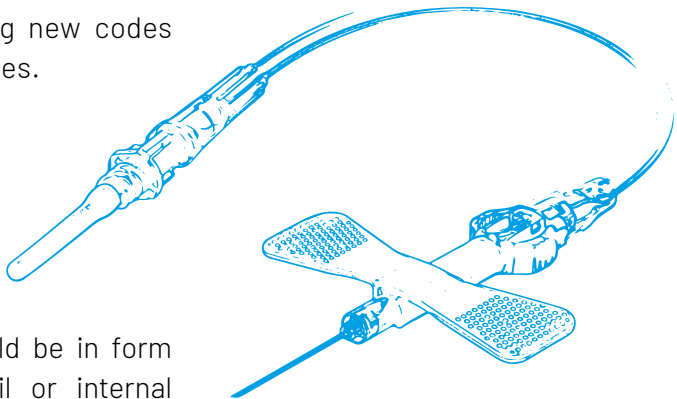
Stock levels will be reviewed in conjunction with Procurement and/or Materials Management Teams and the customer's selected distribution partner on an on-going basis from the award of the contract, with a view to the potential implementation date. It is recommended to roll out the VACUETTE® Blood Collection System as existing stocks (of the current supplier) run out. If necessary, the currently used blood collection system and the newly introduced VACUETTE® Blood

Collection System can be used in parallel. This decision should be based on individual conditions at each laboratory. Once the date has been decided for the start of the implementation, order route and details will be discussed and defined with lead time expectations agreed upon to ensure a seamless supply when transferring from one supplier to another. A Product Matrix can be provided listing all current products with the corresponding new codes and packaging sizes.

## COMMUNICATION – INFORMING END USERS

During the weeks leading up to the conversion, Greiner Bio-One/ the local distributor/laboratory will communicate to all end users, informing them of the change to VACUETTE® Blood Collection


System. This could be in form of a letter, email or internal newsletter. End users will be asked to reduce their stocks to a minimum to reduce any wastage at the time of changeover.



### COMMUNICATION

For assistance, please contact the Technical Service in Austria (faq.pa@gbo.com).





The Greiner Bio-One Training Team is available for support and additional training on-site or online upon request.

## 02. ESTABLISH IMPLEMENTATION PLAN

### PLANNING IMPLEMENTATION DAYS

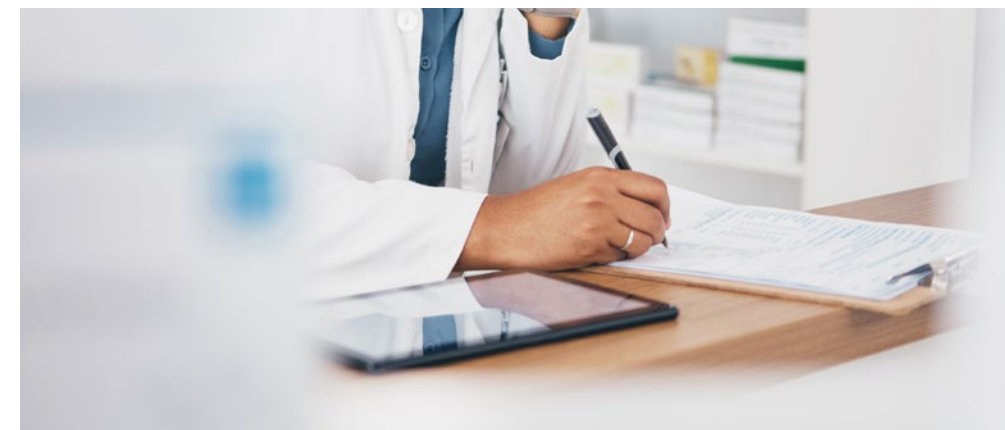
During the implementation days, the Greiner Bio-One Training Team will be available for support and additional training on-site or online, as requested. This is particularly important during conversions due to the need for rapid reactions and, where appropriate, the deployment of additional resources or personnel. Our core philosophy is to have everything in place to ensure the best level of service for customers in the use of the VACUETTE® Blood Collection System. Prior to conversion, each facility will be visited to identify key per-

sonnel who may offer support in introducing the VACUETTE® Blood Collection System.

These could include e.g.:

- / **Laboratory Personnel**
- / **Phlebotomy Manager**
- / **Infection Control**
- / **IV Team**
- / **Procurement**
- / **Supply Chain Management**
- / **Occupational Health**
- / **Head of Nursing**

These are just some examples of the personnel who have helped in the successful implementation of the VACUETTE® Blood Collection System in previous conversions. The structure of each individual site will help decide the final conversion plan. Thus, allowing a partnership between the converted facility and Greiner Bio-One ensuring the conversion is carried out in a professional manner and to the satisfaction of all.



**BEST LEVEL OF SERVICE**  
for customers when using the VACUETTE® blood collection system.



## PLANNING POST IMPLEMENTATION DAYS

In the following days and weeks, Greiner Bio-One will stay in contact with Phlebotomy/Nursing and Laboratory staff, to ensure the change-over is progressing smoothly (and when possible, by circulating around all wards and departments ensuring everyone

is using the system correctly). If any old tubes arrive in the Laboratory, staff is re-trained where necessary and stock changed to the VACUETTE® Blood Collection System. All wards and departments can be re-visited; ensuring everyone is competent using the system.



## 03. TRAINING

### PLANNING TRAINING SESSIONS



Training can be offered, on-site, via the Greiner Bio-One training platform, as well as online.

#### Hospital Wards and Departments:

Typically working with the main contact at the facility, the local Greiner Bio-One company walks the team through recommendations regarding tube verification, emphasizing that it is up to the facility (and their medical director) to determine the path forward for verification.

Training sessions could be arranged at a venue within the hospital, such as a designated room by the hospital over a set period of days during the agreed upon time-period leading up to implementation, if required. Recent conversions have been based upon Hospital "Walk Rounds" where ward/department-based training is provided. With all conversions, the level and number of training sessions are discussed with each site to meet their individual needs. Night shift sessions, Emergency, ITU/ICU and all high dependency areas are contacted to discuss department specific training sessions.

#### Physicians' offices off-site user:

Based on the agreed plan between Greiner Bio-One and the hospital/laboratory in view of the time-period prior to conversion, the local Greiner Bio-One company (sales representative), local distributor or hospital/laboratory will send out a further communication on training details to users.

During the training planning, a person responsible for training at the customer side will be defined. The responsibilities of this individual are to evaluate and authorize training protocols and support the Greiner Bio-One team in organizing training sessions.

This would ensure that training sessions for users who have specific training requirements, are arranged directly with Greiner Bio-One to meet their needs and time restraints, e.g.: remote workers, shift workers etc., where off-site and night sessions will be arranged. Off-site users who are employees of the lab should be involved in the training schedule. An option is a Train-the-Trainer principle, where the trainers are also the key users and the internal contact persons.

Once these sessions have been arranged, the Greiner Bio-One (Sales) Team stays in contact with the main facility contact. Usually, the training requirements differ from product to product (e.g. tubes or safety products). Therefore, the local Greiner Bio-One Team agrees with internal project leader at the facility or head of department (laboratory/blood collection) on the details of training sessions needed.

#### Product Demonstrations:

Greiner Bio-One would plan product demonstrations to identified healthcare staff. As they will be the main users of the new system, it is important that they know what is happening and when. It gives the staff an opportunity to see and learn about the VACUETTE® Blood Collection System and ask questions about their specific requirements. These demonstrations would be planned during the agreed upon time-period leading up to the product changeover.

If possible, Greiner Bio-One would suggest training the Phlebotomists and Nurses so that they use the system in the agreed upon time-period prior to implementation. This gives them time to adjust to the system whilst under no pressure. It also makes other staff aware of the changes that are about to take place.



TRAINING MATERIALS AND SUPPORT -  
VACUETTE® TRAINING RESOURCE TOOLBOX

Throughout the duration of the contract, a representative main contact will keep in periodic touch with Phlebotomy/Nursing and Laboratory personnel to provide further materials and support for training and service, where deemed necessary. Greiner Bio-One takes the issue of training very seriously, offering a fully comprehensive training program. The VACUETTE® Training Resource Toolbox has been developed as an ongoing educational tool for all healthcare workers involved in the preanalytical to analytical phase.

EXAMPLES OF WHAT  
COULD BE INCLUDED  
IN THE VACUETTE®  
TRAINING RESOURCE

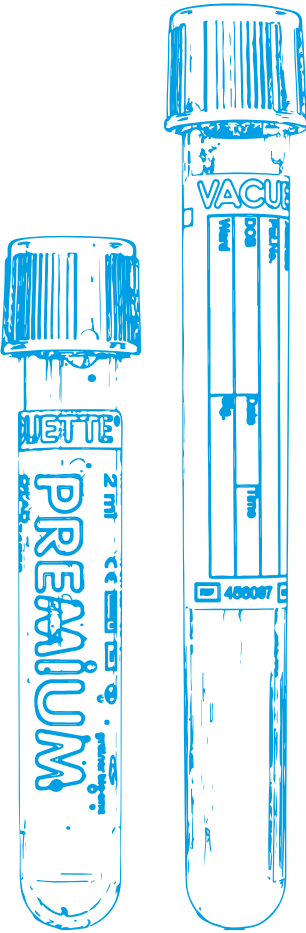
- / Application training slides
- / Presentations
- / Handling Videos
- / User guide booklets

A selection of training materials which will be updated on a regular basis are also available to provide answers to FAQs (see following pages) such as a g-force to rpm graph, order of draw, fill volume levels and other preanalytical variables:

- / VACUETTE® Blood Collection Techniques Booklet
- / VACUETTE® Instructions For Use
- / VACUETTE® Preanalytics Manual

Product handling videos are available online which demonstrate, for example, how each safety device is activated. E-learning courses are available on the Greiner Bio-One online training platform. There are no associated costs for the training and support given by Greiner Bio-One throughout the duration of the contract. Once the training sessions are

completed and all users are ready to use the VACUETTE® Blood Collection System, old stock can be removed or left to be used, dependent on the post award discussions.



THE VACUETTE®  
TRAINING  
RESOURCE  
TOOLBOX

can be used for both  
group and individual  
learning sessions.

IMPLEMENTATION04.

Implementation Support is primarily carried out by the local Greiner Bio-One Representatives or distributor, who have a medical or clinical background who can also be deployed on site. Additional resources and data (e.g. technical specifications, clinical data) can be provided from our Headquarters as needed from:

- / Customer Service
- / Clinical and Technical Specialists
- / Samples Distribution
- / Logistics
- / Marketing Team
- / Research and Development



Support by local Greiner  
Bio-One representatives or  
distributors who have a  
medical or clinical background.



We empower  
people, who  
work in health.



## FOLLOW-UP 05.

### POST IMPLEMENTATION

Upon completion of the agreed implementation plan, a review meeting can be scheduled with the customer. This meeting could cover:

- / **Current status**
- / **Feedback and adoption**
- / **Tasks or issues arising or outstanding**
- / **Points to be addressed**
- / **Creation of forward action plan**

Greiner Bio-One staff will be available as needed, as mutually defined between Greiner Bio-One and the customer during the agreed upon time-period following conversion to follow up on adoption with end users and key stake holders and address any immediate needs. Staff will have access to the Greiner Bio-One account managers contact details for prompt responses.

### POST IMPLEMENTATION TRAINING AND SUPPORT

Once the full conversion to the VACUETTE® Blood Collection System has taken place, ongoing training will be provided, utilising the VACUETTE® Training Resource Toolbox (as available and defined). This can be useful in the following areas, for example:

Follow-up training on the VACUETTE® Blood Collection System

- / **New staff**
- / **New VACUETTE® products**

All VACUETTE® training and support complies with CLSI (Clinical Laboratory Standards Institute). Greiner Bio-One value training and support as an integral part of any product related contract offering a fully comprehensive training program, which has been implemented successfully during and post conversion for VACUETTE® users. Members of the Greiner Bio-One (training) team would be available and support where required, dependent on the location to facilitate any conversion.

# MOST FREQUENTLY ASKED CONVERSION QUESTIONS

## When converting from another manufacturer’s tubes, what steps are necessary to verify the performance of Greiner Bio-One VACUETTE® Blood Collection Tubes and to satisfy regulatory requirements?

CLSI has published a guidance document (GP34-A; Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection) on tube verification to assist end users with this process. Verification testing should include method comparison with representative analytes between your current tube and the Greiner Bio-One sample collection system. If desired, within-tube precision can be determined by performing duplicate analyses during the method comparison. The number of samples tested should be sufficient to be statistically valid. A minimum of 20 samples is typically required, though most laboratories prefer 30 to 40 samples.

## How much will it cost to perform an evaluation (testing appropriate for verification purposes) in my laboratory?

Cost of evaluation testing is derived from the cost of the tube, the cost per test (or cost of reagent per test), the average hourly pay rate of the technologists in your laboratory and the estimated time to run each test.

## What is required if tubes are centrifuged at a different time or g-force than what the Instructions for Use (IFU) recommend?

Many labs are limited by centrifuges unable to achieve the recommended g-force or have turn-around-time constraints that do not allow for the recommended time. Centrifugation of tubes outside the manufacturer’s recommendation is considered as off-label use and requires testing to validate that deviations from the manufacturer’s recommendations do not affect analytical outcome. This testing should include a method comparison with representative analytes and a minimum of 20 samples. Frequently, there are already studies available to support the adaption of centrifugation conditions.

## Are the tubes of Greiner Bio-One VACUETTE® Blood Collection System validated on the instrument platforms in my laboratory?

Greiner Bio-One works very closely with instrument manufacturers to ensure that tubes of Greiner Bio-One VACUETTE® Blood Collection System are compatible with the instrument platforms utilised in the clinical laboratory. In some cases, Greiner Bio-One can provide documentation from the instrument manufacturer indicating that specific tubes are approved for use. However, some manufacturers simply publish physical specifications of tubes appropriate for their instrumentation in the instrument manual or literature.



### What resources can Greiner Bio-One process?

The local Greiner Bio-One Application Specialists can assist you in making the change to Greiner Bio-One VACUETTE® Blood Collection System successful. We also offer educational material and literature that can be used for your purposes that is beneficial during the implementation process as well as ongoing training.

## CHECKLIST

The following checklist can be used to follow each step

1.  
☒

Instrument Compatibility for VACUETTE® Blood Collection System checked

2.  
☐

Laboratory inspection done (if needed by a vendor representative)

3.  
☐

Instrumentation and centrifugation settings applicable to VACUETTE® Blood Collection System

4.  
☐

Stock levels reviewed

5.  
☐

Ordering details discussed

6.  
☐

First order placed

7.  
☐

All end users informed

8.  
☐

Training session planned

9.  
☐

Information material provided (supportive literature, examples)

10.  
☐

Close contact with Phlebotomy, Nursing and Laboratory Staff to ensure everyone is using the system correctly

### SUPPORTING DOCUMENTATION:

- GP34-A Vol.30 No. 25 Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection, Approved Guideline (2010), Clinical and Laboratory Standards Institute
- Lippi et al, EFLM WG-Preanalytical phase opinion paper: local validation of blood collection tubes in clinical laboratories, Clin Chem Lab Med 2016
- EP28-A3c Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition (2010), Clinical and Laboratory Standards Institute
- EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples – Third Edition (2018), Clinical and Laboratory Standards Institute



# making a difference

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**GREINER BIO-ONE IS A GLOBAL PLAYER.**  
FIND THE CONTACT DETAILS OF YOUR  
LOCAL PARTNER ON OUR WEBSITE.



This product information is addressed exclusively to healthcare professionals.  
Devices of Greiner Bio-One are to be used by properly trained healthcare professionals only in accordance with the relevant Instructions for Use (IFU). For a listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompanies each product. For more information contact your local Greiner Bio-One sales representative or visit our website.

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