# Supplier Questionaire

## Information on the supplier evaluation

### General Information

Company:

Bioanalytic GmbH
Waldmatten 10-13
79224 Umkirch/Freiburg i. Br.
Germany

Branch of industry:

Biomedical and analytical chemical reagents, medical laboratory diagnostics, in vitro diagnostics (IVD), biomedical science & analysis technology, biotechnology and life science.

Manufacturing Site Operation:

Manufacturer.

Does Bioanalytic GmbH do primary manufacturing?

Yes.

Does Bioanalytic GmbH do OEM manufacturing?

Yes.

### Certifications & Quality Management

Does Bioanalytic GmbH have certifications and a certified quality management system?

Yes. Bioanalytic GmbH is fully certified in accordance with EN ISO 9001 (quality management) and EN ISO 13485 (medical devices). Please download certificate: www.bioanalytic.de > Download > Certificates

Does the certification apply to the whole company?

Yes. Bioanalytic GmbH is certified for all areas: development, manufacturing and distribution.

Is your company registered with the FDA?

Yes.

Who is responsible for quality assurance?

Manfred F. Rüdinger (Production Manager)
Dr. Ferdinand M. Rüdinger (Quality Manager)

### Manufacturing

Are established written procedures for each product manufactured?

Yes.

Do you have a batch record for each batch/lot manufactured?

Yes.

How long do you keep the batch records?

≥ 10 years.

Do you retain samples? How long?

Yes. At least until the specified expiry date.

Do you manufacture products corresponding to national/international guidelines and state of the art?

Yes.

Is there traceability to all raw materials used during the manufacturing process?

Yes.

Does Bioanalytic GmbH issue a unique lot or batch number for each production run?

Yes.

Is a complete record of production activities maintained for
a) Line clearances/cleaning between production runs?

Yes.

b) Deviations from process specification requirements?

Yes.

c) Rework or reprocessed product?

Yes.

Are there any precautions to avoid foreign particles in the finished product?

Yes. Specified for each product.

Does Bioanalytic GmbH have established a change control system to document changes in the process or the product?

Yes. Database based.

Is there a process or procedure to control packaging and labeling components?

Yes. Database based.

Are written instructions available for packaging components, packaging operation, label and labeling?

Yes. Database based.

Are you prepared to meet packaging and labelling requirements from your customers?

Yes. We are specialized for OEM to PLM manufacturing.

Do you maintain lot separation during packaging?

Yes. This is a statutory requirement.

Are laboratory animals used for research, development and production?

No. Our products are developed, made and tested without any animal experiments.

Are there written procedures for controlling items with shelf-life and storage requirements?

Yes.

Are specifications of the products available?

Yes. Depending on products and requirements.

Is there a regular update of the specifications?

Yes.

Do you supply Certificates of Analysis (CoA) for each batch and are actual analytical results included?

Yes. Depending on products and requirements.

Do you supply Certificates of Conformity?

Yes. Depending on products and requirements. For example: IVD (In vitro diagnostics) are CE certified according EG Directive 98/79/EG.

Do you supply Safety Data Sheets?

Yes. Saftey Data Sheets are available via international and worldwide valid SDS-ID on www.sds-id.com.

Are products rotated on a first in, first out (FIFO) or first expiry, first out (FEFO) basis?

Yes.

Do you ship your products internationally?

Yes.

### Material Control

Is a list of approved suppliers maintained?

Yes.



Bioanalytic GmbH
● biomedical & analytical chemical reagents • medical laboratory diagnostics
● in vitro diagnostics (IVD) • biomedical science & analysis technology
● Waldmatten 10-13 • 79224 Umkirch/Freiburg i. Br. • Germany

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E-Mail: office@bioanalytic.de
Internet: www.bioanalytic.de

Are checks of incoming materials carried out? / Do you have procedures for the control of raw materials?

Yes. Spezified for type of materials.

Are raw materials/commodities evaluated for acceptability prior to use?

Yes.

Is there a process for managing discrepant or nonconforming materials?

Yes.

Are materials rotated on a first in, first out (FIFO) or first expiry, first out (FEFO) basis?

Yes.

## Quality Control and Quality Assurance

Are there written procedures for testing and are there formal written procedures for all performed tests?

Yes.

Is your quality control independent from production?

Yes.

Do you test sterility of your sterile products or are you capable doing so?

Yes. The CoA contains a reference to aseptic production.

Are there written procedures for handling Out of Specification (OoS) results?

Yes.

Are there established procedures for the calibration / maintenance of laboratory equipment and measureing devices?

Yes.

Are test results traceable to the lot or batch produced?

Yes.

Does a qualified person review the batch records before the batch is released and certified?

Yes.

Is the decision to release or reject a product for sale independent from production?

Yes.

Is there an established periodic pest control?

Yes.

## Complaints and Recall

Is there a formal complaint procedure?

Yes.

In what time period would you normally reply to a formal complaint?

Immediately, within 24 hours.

Is there a recall policy?

Yes.

## Facility and Utilites

Were the premises designed for the present use?

Yes.

Are separate areas for storage of chemicals, manufacturing, approved finished products as well as packaging and dispach existing?

Yes.

Are the working-rooms of Bioanalytic GmbH of proper size for the intended function and satisforctorily lighted?

Yes.

Are the working-rooms of Bioanalytic GmbH supplied with security and fire protection systems?

Yes.

Is a recreation room available?

Yes.

Are plant supply pipelines identified and labelled?

Yes.

Do you monitor the quality of the water used to prepare standards and reagents?

Yes.

Do you monitor the quality of the water used during the manufacturing process?

Yes.

## Machines and Equipment

Is there a maintenance and preventative maintenance program for all pieces of equipment?

Yes.

Do you have written maintenance and calibration procedures for critical equipment?

Yes.

Do you retain records of calibration as evidence of control?

Yes.

Is there a cleaning plan/procedure for production machines, equipment?

Yes.

Have the cleaning and sterilisation processes been validated?

Yes.

Do you have a documented procedure for the validation of all test and measuring equipment used to demonstrate the conformance of product to the specified requirements?

Yes.

Do you retain records of validation as evidence of control?

Yes.

## Environment

Do you have an environmental policy?

Yes. Environmental protection is especially important to us. We act in the consciousness of responsibility for our environment.
www.bioanalytic.de > Company > Environment & Energy

Is the company operating an environmental management system such as ISO 14001?

Bioanalytic GmbH operates internally an environmental management system oriented according to DIN EN ISO 14001.

Are there any environmental initiatives that you are carrying out e.g., reducing energy/water consumption?

We use 100 % of electricity from renewable energy sources (such as hydroelectric, wind and/or solar energy) in all departments: administration, production, warehouse. etc. We avoid unnecessary energy consumption as far as possible through appropriate technologies.
We use water resources carefully and avoid unnecessary water consumption.
To conserve our natural resources we keep our paper emissions as low as possible. Therefore, our products contain no information in a variety of languages, but they are available on our website for free download.
In addition to recycling and waste minimization, we attach great importance to the ecological care of our company areal. Appropriate planting and a forest and pond area provides habitat for many animals, especially lizards, snakes, amphibians, fish, birds and small mammals.

## People & Human Rights

Does Bioanalytic GmbH have an environmental health & safety policy, which includes training for employees?

Yes.

Are there documented periodic inspections to verify the EHS policy is functioning correctly?

Yes.

Does Bioanalytic GmbH provide suitable personal protective equipment for employees e.g., eye, foot, skin, breathing or hearing protection?

Yes.

Does Bioanalytic GmbH have a fully operational fire safety system including fire alarm, fire extinguishers and unlocked exits?

Yes.

Do you have an adequate emergency response plan and organisation?

Yes.

Does Bioanalytic GmbH ensure that employees are aware of/ understand any risks involved with their work and how to minimize or eliminate these risks?

Yes.

Does Bioanalytic GmbH ensure that there is no discrimination in hiring, compensation, access to training, promotion, termination or retirement based on race, caste, national origin, religion, age, disability, gender, marital status, sexual orientation, union membership or political affiliation?

Yes. See code of conduct.

Does Bioanalytic GmbH ensure that no harsh or inhumane treatment of employees is allowed, this includes physical abuse or discipline, the threat of physical abuse, sexual or other harassment, verbal abuse and otherforms of intimidation?

Yes. See code of conduct.

## Personnel, Training and Education

Do you have procedures that document how you perform training?

Yes.

Do you maintain records of the training?

Yes.

Specific training e.g. aseptic working or handling toxic materials?

Yes.

Periodic assessment of practical effectiveness?

Yes.

Periodic refresher training programs for established employees?

Yes.

At the start of new product manufacturing?

Yes.

When new methods are used?

Yes.

Quality techniques for production people?

Yes.

Does your training program emphasise product integrity, saftey, hygiene and cleanliness?

Yes.