QUALITY MANUAL

VERSION 2
REVISION 7

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QUALITY MANUAL CONTENTS

ITSI-Biosciences, LLC Quality Policy:

ITSI-Biosciences is a contract research and professional service organization that provides quality services and products at a competitive price and turn around time. All laboratory activities are carried out under strict Good Laboratory Practice (GLP) and strict confidentiality conditions. The quality of our products and services is of primary importance to our company and is something we are always striving to improve upon.

ITSI-Biosciences has created a high quality work environment with the highest standards concerning quality assurance. It is every employee's personal responsibility to assure the quality of all of our services and products. ITSI-Biosciences operates in accordance with the highest expected standards of integrity, education, organization, excellence, safety, quality assurance and quality control.

ITSI-Biosciences (www.itsibio.com), the Lifesciences Division of Integrated Technologies & Services International (ITSI; www.itsi.us) started full operations in January, 2005. ITSI-Biosciences is a high throughput bioanalytical service and bioreagent manufacturing company with head office in Johnstown, PA, USA. The ITSIBIO team members are experienced biomedical research scientists with broad cognate experience and over 35-years combined molecular biology, genomics, molecular biology, biochemistry and proteomics experience in academia and industry.

By serving as an extension of the laboratory of researchers for outsourced analytical services, ITSI-Biosciences helps researchers instantly expand their capabilities and productivity. This prevents researchers from incurring the burden of additional personnel and/or capital equipment costs. Although ITSIBIO performs the work, the investigator owns all the data generated and all the information exchanged and transactions are conducted under strict confidence. Our core analytical services include global gene and protein expression profiling, biomarker monitoring and validation, protein identification by mass spectrometry, targeted genomics and proteomics, and assay development and optimization. Most biological and clinical samples can be analyzed by ITSI-Biosciences; including tissue homogenate, flash frozen tissue, cell lysate, serum, plasma, urine, saliva, formalin-fixed paraffin-embedded samples, purified DNA, RNA and protein. Microbial, agricultural and plant products can also be analyzed at ITSI – Biosciences at the DNA, RNA and protein levels. The distinctive Two-Dimensional Difference in Gel Electrophoresis (2D-DIGE), Isobaric Tag for Relative and Absolute Quantitation of proteins (iTRAQ) and Multi-Analyte Protein profiling (xMAP) technologies are used for multiplexed protein quantitation and the QuantiGene technology is used for multiplexed nucleic acid quantitation.

ITSI-Biosciences also develops environmentally safe easy-to-use kits for sample preparation as well as recombinant proteins and antibodies for biomedical research. Specifically, ITSI-Biosciences provides better and affordable ready-to-use reagents for protein isolation, protein quantitation, protein fractionation, protein digestion monitoring, protein precipitation and protease inhibition. Our ITSIPrep ready-to-use reagents, buffers and standardized/validated protocols help users perform experiments faster, accurately and conveniently. These distinctive ITSIPrep Kits help eliminate protein breakdown attributable to poor quality reagents while reducing the overall cost of sample preparation and performance of experiments because of the time and materials saved in making home-brew buffers and reagents.

A major responsibility of ITSI-Biosciences' management is to ensure that all the ITSIBIO employees are conversant with company Quality Policies and strictly adhere to established procedures and protocols for assuring and controlling quality.

ITSI-Biosciences core management team consists of the following, which are responsible for the quality of the products and services of ITSI-Biosciences.

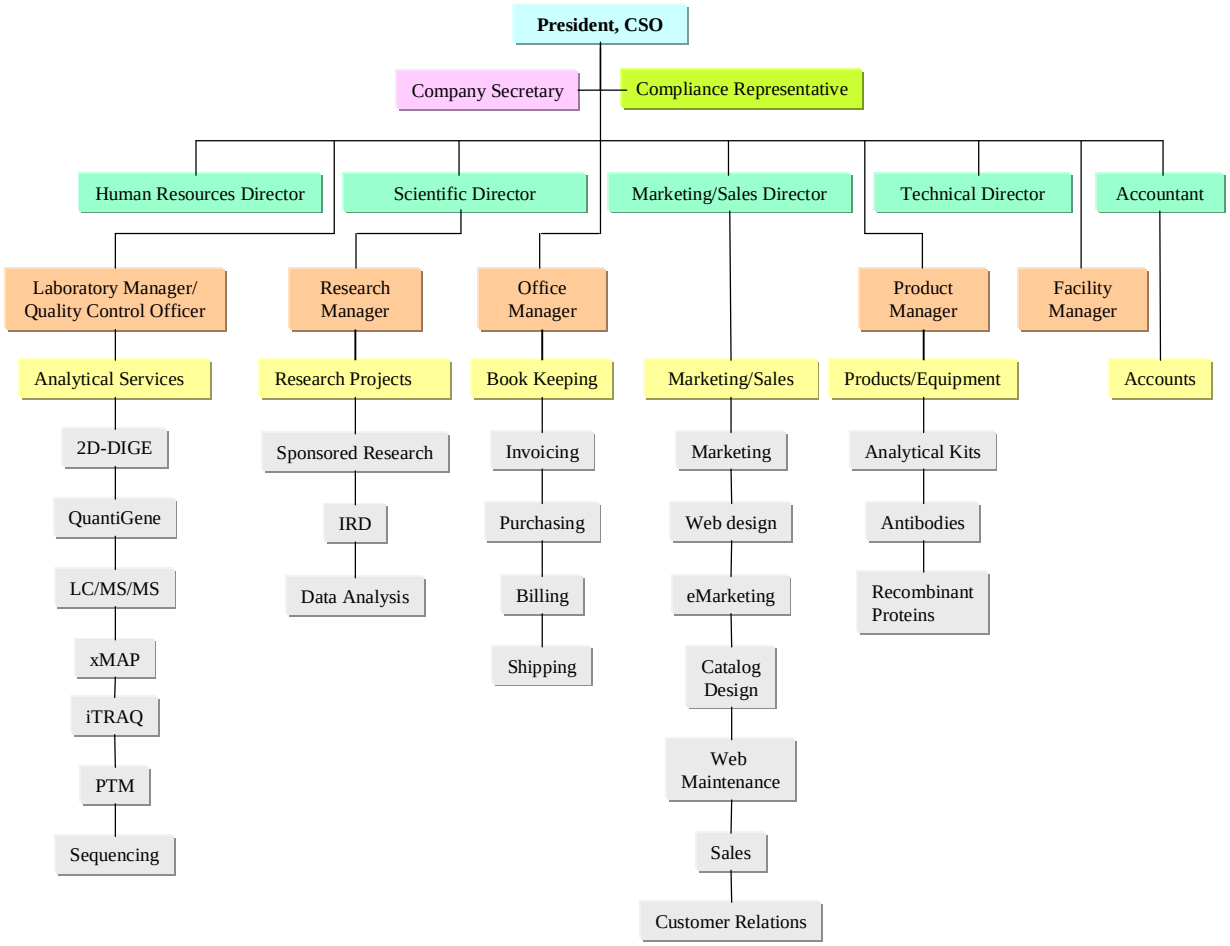
- The President/CSO. He/She must create an environment where quality is the number one priority and have the final responsibility for seeing that policies are adhered to.
- The Scientific Director or a designated Safety Officer. He/She is directly responsible for monitoring the implementation of quality and safety policies on a day-to-day basis. He/She ensures that all personnel work in a safe environment and totally adhere to ITSI-Biosciences Quality and Safety policies. He/She must perform random checks/audits to guarantee that all guidelines are being followed properly.
- The Technical Director. He/She must make sure that all equipment are certified and maintained regularly. This position also oversees all technical issues in the company.
- The Office Manager/Administrative Assistant. He/She is responsible for the quality of the workflow process in the front office and integrates this process with activities in the laboratory. This position oversees purchasing, bookkeeping, and customer relations and is a link between administration, business development, marketing/sales, scientists and customers.
- The Laboratory Manager. He/She must make sure that all laboratory activities are carried out according to the highest quality standards.
- The Compliance Representative. He/She ensures that quality systems are maintained, implemented and reviewed continuously. He/She must perform corrective and preventive actions for any quality-related issues. Periodic inspections and testing at all levels of the production and services must be done by the quality control/assurance manager. He/She must regularly review the quality systems to try improving upon the quality standards that are put in place. Any issues in quality must be reported to upper management immediately.

Although management is generally in charge of assuring quality throughout the organization, it is the responsibility of every employee to ensure the quality of his or her individual work and to diligently abide by all ITSI-Biosciences' policies.

Related Documents:

200432 - Quality System Review

The following chart illustrates the organizational structure of ITSI-Biosciences for operations. This structure allows us to run as an efficient entity with quality as the number one objective.



ITSI- Biosciences Organizational Structure for operations.

Legend:

- xMAP – Multi Analyte Profiling using magnetic bead technology – Used for multiplexed protein analysis.
- 2D-DIGE – Two Dimensional Difference in Gel Electrophoresis – Used for global analysis of proteins and identification of differentially expressed proteins.
- QuantiGene – A magnetic bead based technology for multiplexed analysis of RNA.
- LC/MS/MS – Liquid Chromatography – Tandem Mass Spectrometry – Used for sequencing and identification of proteins.
- iTRAQ - Isobaric Tag for Relative and Absolute Quantitation of proteins – a mass spectrometer based approach for absolute quantitation of proteins.
- PTM – Post Translational Modification analysis.
- IRD – Internal Research & Development.

ITSI-Biosciences' Quality System covers every aspect of the company's operation, including the products we make and the services we provide. This system is composed of three parts: a) Quality Manual, b) Operating Procedures, and c) Quality Audits.

a) The Quality Manual gives a detailed description of the company's quality policy, profile, and specific procedures used throughout the company that must be followed.

b) The Operating Procedures are documents that describe all the guidelines and procedures that apply directly to the specific processes performed at ITSI-Biosciences. They are listed throughout this manual, but can also be found in the laboratory office, company server and website (www.itsibio.com).

c) The Quality Audits are audits performed by a Quality Control and/or Compliance Officer appointed by management. These audits are completed following the guidelines in the Quality Manual. The results are reported to the President and it is the responsibility of the officer to develop any corrective measures to ensure that the quality of our products and services is upheld at all times. In addition to routine audits, the Quality Control and/or Compliance Officer must review the Quality System annually. This review must contain the results of the routine audits and provide the solutions to any quality issues found in the audits. The review will be written in a report and given to the President for any further improvements.

Presently, the Laboratory Manager is the designated Quality Control Officer at ITSI-Biosciences.

Related Documents:

200456 - Quality Audit Reports
200432 - Quality System Review

ITSI-Biosciences' Quality Control Officer ensures that all procedures related to quality of operations are controlled, revised and reissued, and archived properly.

The following are documents that must be controlled:

- Chemical Hygiene Plan
- Equipment Calibration and Maintenance Records
- Forms
- Manuals
- Personnel Information
- Product Production Logbook
- Product Validated Biolab Procedures
- Project Folders
- Protocols
- Quality Audit Reports
- Standard Operating Procedures
- Subcontractor List
- The Quality Manual
- Vendor List

Any changes to the above documents must be reviewed and approved by the Quality Control Officer before it is made a permanent addition to the procedures.

Related Documents:

200456 - Quality Audit Reports
200412 - ITSI General Laboratory Handbook
200486 - DIGE Manual Abbreviated Version
200447 - Ettan DIGE Manual
200455 - 2-D Electrophoresis
200421 - Spot Picker/Digestion Manual
200413 - Luminex-xMAP
200466 - Typhoon
200472 - Agilent 2010 Bioanalyzer
200487 - Product Production Logbook
200427 - Project Folders
200491 - Product Validated Biolab Procedures
200446 - ITSI CHP
200419 - Report SOPs
200406 - Product SOPs
200484 - Equipment Calibration and Instrument Maintenance
200415 - Sample Receiving Protocol
200401 - Incident Report Form

ITSI-Biosciences provides quality products and services, both of which are tailored to the customers needs. All of our core products and services are listed on our website and in our catalog. Our services are unique and differ from customer to customer; therefore, a specific quote is required for each service.

When ITSI-Biosciences' services are requested, a sample submission form is filled out by the customer. The form is available online at www.itsibio.com and can be sent by fax or email to potential customers. After review of the completed form, an initial project proposal, which states the exact services to be done is prepared and sent to the customer for approval. Under normal circumstances, the project will not start until the proposed approach described in the initial project proposal is approved by the client. During the project, if there are any deviations from the approved project proposal, the customer will be notified and the issues resolved so that the customer will be completely satisfied. If a customer requests additional work on a project, a new quote will be developed and sent to the customer, followed by another (initial) project proposal.

When customers send samples to ITSI-Biosciences for analysis they are expecting and receiving the highest quality of analytical service available.

ITSI-Biosciences have specific protocols for receiving samples and this must be followed diligently by all ITSI-Biosciences employees to ensure that the integrity of the samples received is maintained. Once the samples are processed, the report and invoice submission is produced following the strict protocol/procedures laid out at ITSI-Biosciences.

All of the information pertaining to each project is kept in a separate digital project folder found on the ITSI-Biosciences server. Paper copies are also retained in the laboratory office in a binder. Data generated for clients are held in strict confidence and stored at ITSI – Biosciences for a minimum of five (5) years before they can be discarded.

Related Documents:

200415 - Sample Receiving Protocol
200419 - Report SOPs
200427 - Project Folders

ITSI-Biosciences only works with subcontractors that supply the highest quality work or products that is equal to ITSI-Biosciences' standards. Subcontractors are carefully vetted and sometimes their facilities are visited and inspected by ITSI-Biosciences employees. When a subcontractor is required for an aspect of a project, ITSI-Biosciences will inform the customer by including this information and the name of the subcontractor in the initial project proposal. If subcontracting is not necessary in the beginning of the project but becomes needed after the project starts, a new initial project proposal will be sent to the customer for approval before continuing with the project.

All of the relevant information about the subcontractors used by ITSI-Biosciences can be found in a subcontracting folder on the ITSI-Biosciences server and in the laboratory office.

To facilitate availability and delivery of our quality products and services globally, we have multiple distributors throughout the world. We have set in place strict guidelines for potential distributors that must be maintained at all times. Periodic information and questionnaires are given to the distributors so that we can provide the best quality products and services to our customers worldwide.

Related Documents:

200463 - Subcontractor List
200482 - Distributors
200453 - Distributor Surveys

At ITSI-Biosciences the quality of raw materials is essential to maintain the highest standard of quality throughout our company. A complete list of qualified vendors is maintained. To make the list, the vendor must have a quality system in place and adhere to good laboratory/manufacturing practice. All vendors that supply substandard products, or products with questionable quality are removed from the list and blacklisted.

The following is the purchasing procedures used at ITSI-Biosciences:

1. All employees at ITSI-Biosciences can complete a Requisition Form to obtain a Purchase Order.
2. The Requisition Form must be signed by a supervisor before any item can be purchased. The Requisition Form contains all the necessary information including the product number, vendor name, cost, quantity and cost center or project number. Ordering is only done on Tuesdays, so requisition forms must be given to the Office Manager or Lab Manager no later than Friday for items expected to be ordered the following week.
3. Once a Requisition Form has been signed and submitted, a Purchase Order is created and the item can be ordered.
4. When the item arrives at ITSI-Biosciences it is cross-checked with the Purchase Order using the packing slip. If the product is non-conforming or damaged, the vendor is notified immediately.
5. The items ordered are logged in the inventory section of the Laboratory Management Database before being stored in the laboratory or supply room.

Related Documents:

200451 - Vendor List
200422 - Requisition Form
200477 - Laboratory Management Database Manual
200433 - Purchase Order Form

In order to maintain the highest quality standards ITSI-Biosciences encourages customers to send feedback and complaints to management.

ITSI-Biosciences has a specific Product/Service Review Form that is given to some randomly selected customers 30 days after the purchase of a product or service. This form is reviewed and if necessary, changes are made to improve the quality of ITSI-Biosciences' products and services. All review forms are re-evaluated during the weekly company meetings to ensure that solutions have been made so that our products and services are of the highest quality and standard, and the customer concern is addressed.

If a customer has a complaint against any product or service, immediate action is taken by the appropriate party to rectify the situation. All complaints are maintained in a log or database in the office for future reference.

ITSI-Biosciences has both a Facebook page and Twitter page open to the public. This allows our customers to leave us feedback about our products and services at any time. These pages are maintained by our marketing department and monitored daily.

Related Documents:

200405 - Product/Service Review Form
200418 - Customer Complaints

If a non-conforming product is identified at ITSI-Biosciences, our quality system takes the appropriate action, including identification, segregation, and disposition of the non-conforming product.

All non-conforming products are clearly marked once they are identified and are not used until a review of the product is performed. A Non-conforming Product Form must be filled out immediately and given to either the Laboratory Manager or the Office Manager.

To ensure proper rectification of the non-conforming product, a review and re-inspection of the product is performed and documented by the Quality Control Officer.

Related Documents:

200426 - Non-conforming Products

ITSI-Biosciences prides itself as an organization that makes quality products and provides quality services; therefore, when corrective and preventive action are required, ITSI-Biosciences immediately takes the necessary steps to resolve any issue associated with the problem.

Once the problem has been identified on the Non-conforming Product Form, the corrective action is monitored closely by the Quality Control Officer.

The Quality Control Officer is responsible for evaluating and documenting the progress of the corrective or preventive actions.

After 30 days from the resolution of the problem, a review and documentation of the product or service is required by the Quality Control Officer to ensure continued complete customer satisfaction.

Corrective and preventive action is not limited to the Quality Control Officer. All employees at ITSI-Biosciences are encouraged and expected to suggest improvements on all aspects of both products and services.

Related Documents:

200499 - Corrective/Preventive Action
200426 - Non-conforming Products

Record keeping at ITSI-Biosciences is taken seriously. All units and departments diligently keep records. The following are quality records maintained at ITSI-Biosciences:

- Chemical Hygiene Plan
- Contracts
- Corrective/Preventive Action Reviews
- Customer Complaints
- Equipment Calibration and Maintenance Records
- Non-conforming Products
- Personnel Records
- Product Production Logbook
- Product/Service Reviews
- Project Folders
- Purchase Orders
- Quality Audits
- Quality Manual
- Requisition Forms
- Standard Operating Procedures
- Subcontractor/Vender Qualifications
- Training Records
- Validated Biolab Procedures

All our records are properly preserved and easily accessible by designated personnel. All records are retained for a minimum of 5 years.

Related Documents:

200456 - Quality Audit Reports
200445 - Chemical Hygiene Plan
200427 - Project Folders
200424 - Contracts
200484 - Equipment Calibration and Instrument Maintenance
200487 - Product Production Logbook
200491 - Validated Biolab procedures
200405 - Product/Service Review Form
200418 - Customer Complaints
200426 - Non-conforming Products
200499 - Corrective/Preventive Action
200463 - Subcontractors
200433 - Purchase Orders
200468 - Personnel Records
200439 - Training Records

To maintain the highest quality for our products and services, ITSI-Biosciences management is required to conduct a review of the Quality System at least once a year. The details of the meeting are recorded and kept on hand in the laboratory office.

The objectives of the Management Review Meeting include:

- Establishing that the Quality System is accomplishing the goals of ITSI-Biosciences concerning the quality of its products and services.
- Identifying any weaknesses in the Quality System and providing immediate solutions to those issues.
- Reviewing the corrective actions taken and making sure that any issues involved were resolved and that the actions will prevent future problems.
- Evaluating any complaints processed and determining the root of the problem so that the situation is resolved and recurrence prevented.
- Reviewing the results of the routine quality audits and annual quality manual review performed by the Quality Control Officer to determining if there are any recurring issues and providing solutions for these issues.
- Identifying the non-conforming products and providing improvements on these products.

Related Documents:

200459 - Management Review
200456 - Quality Audit Reports
200432 - Quality System Review
200418 - Customer Complaints

ITSI-Biosciences hires only qualified personnel and provides all the necessary support and training to ensure that he or she functions optimally. All ITSI-Biosciences employees are able to fulfill the technical, educational and experience requirements that allow ITSI-Biosciences to provide quality products and services on time.

The ITSI-Biosciences server contains copies of job descriptions, resumes and performance reviews of each employee. The ITSI-Biosciences Employee Handbook explains all of the policies and procedures of ITSI-Biosciences.

A tailored training program is implemented when a new employee is hired. Once the program is complete, the employee and a supervisor must sign the training program before the employee can begin work. If necessary, additional training outside ITSI-Biosciences is provided to the employee.

Mandatory safety training, including training on emergency situations, and Good Laboratory Practice is required by each employee before beginning work in the offices or laboratory.

It is the responsibility of the office officer, laboratory manager, and supervisors to recommend additional training as may be required of all employees when needed.

Related Documents:

200470 - ITSI Employee Information
200495 - ITSI Employee Handbook
200442 - ITSI Training Program
200443 - Performance Reviews
200461 - Emergency Safety

The ITSI-Biosciences building was completed in 2009. The facility is a Green Building (L.E.E.D. – Leadership in Energy & Environmental Design) designed to LEED "Silver" status. ITSI-Biosciences laboratory has a heating and ventilation system that maintains a constant temperature, airflow and pressure that is comfortable for the employees and conducive for laboratory operations. The laboratory pressure system is monitored daily by three pressure gauges strategically located in the laboratory and corridor. Additionally, ITSI-Biosciences has an integrated Cleanroom that is ISO Class 6 (FS209e Class 1,000) certified in an "At-Rest" mode of operation at 0.5 microns. Specific instructions are kept in the laboratory office about the use and restrictions of the Cleanroom. ITSI-Biosciences' laboratory contains a laminar flow hood used for sensitive samples and testing. There is also a chemical hood for use with reagents and chemicals that produce fumes.

Appropriate chemical safety standards are maintained and as such all chemicals, general reagents, and laboratory materials are properly stored in designated areas according to the manufacture's label. All chemicals and reagents are dated when received from the manufacturer and when first opened. All products produced by ITSI-Biosciences are marked with an expiration date and packaged and transported to uphold the highest quality standard of the product. A record is kept of the preparer and inspector of each product produced.

ITSI-Biosciences has a standby gas-powered generator that supplies emergency power when needed. There are designated emergency outlets and selected equipment that must remain on always, e.g. freezers, mass spectrometers are connected to such outlets so that they do not lose power in the event of a power failure. There is a specific procedure to follow by all employees in case power outage. To ensure that the emergency generator is in good working condition and available on-demand it is programmed to turn-on automatically weekly on Thursday's at 8AM and run for 20 min, and shot down automatically.

Access to the ITSI-Biosciences' and laboratory is controlled. Access to the laboratory is restricted to employees only. A Visitor Log is maintained in the front office.

Related Documents:

200474 - Cleanroom Manual
200497 - Chemical Inventory
200489 - Safety Manual
200429 - Visitor Log

All laboratory methods used at ITSI-Biosciences have been tested and validated according to internal and industry standards. All of ITSI-Biosciences equipment have protocols for regular operation and maintenance. The protocols used in the laboratory can be accessed at any time and are located in the laboratory office. It is the job of the Laboratory Manager or Quality Control Officer to maintain the latest version of all protocols in the laboratory. Any deviation from the accepted protocol must be documented and reviewed by the Laboratory Manager, supervisor or Quality Control Officer and validated before it can be followed by the ITSI-Biosciences employees. The customer will also be notified if any changes occur to an original protocol discussed and acceptance of the new protocol must be obtained before proceeding with the customers experiment. All data collected during a procedure is stored and processed with the customer's confidentiality in mind.

When any product or reagent is manufactured for in-house use, all bottles are labeled with the necessary information to maintain the quality of the product. Additionally, all the standard materials and reagents used for validation of the methods are properly recorded, including lot number.

Any new method used for current procedures and products developed at ITSI-Biosciences must be validated before being used in the laboratory. Records of performance verification are kept for future reference.

Related Documents:

200486 - DIGE Manual Abbreviated Version
200447 - Ettan DIGE Manual
200455 - 2-D Electrophoresis
200421 - Spot Picker Manual
200413 - Luminex-xMAP
200466 - Typhoon
200472 - Agilent 2010 Bioanalyzer
200484 - Equipment Calibration and Instrument Maintenance
200427 - Project Folders
200409 - New protocols

Because ITSI-Biosciences prides itself on quality products and services, only the highest quality equipment is used in the laboratory. All equipment used at ITSI-Biosciences is subject to either routine or periodic calibrations, depending on the specific equipment. A unique calibration protocol is used for each specific piece of equipment found in the laboratory. All results of the calibration testing are recorded and reviewed by the Quality Control Officer to ensure that the equipment is functioning properly.

In addition to routine calibrations performed by the laboratory personnel, the Quality Control Officer performs intermittent calibrations to make certain that ITSI-Biosciences is providing the highest quality products and services.

All equipment used at ITSI-Biosciences is cleaned frequently to maximize the performance of all the equipment. Additionally, routine safety checks are performed to ensure that all equipment are safe to use by ITSI-Biosciences employees.

A record is kept of all the important information about each individual piece of equipment.

Related Documents:

200484 - Equipment Calibration and Instrument Maintenance
200437 - Instrument Information
200493 - Safety Checks

In order to maintain ITSI-Biosciences' goal of generating quality and error-free results our results and reports are rigorously tested and reviewed before they are sent to customers.

The results generated at ITSI-Biosciences are of the highest quality because of the following factors:

- ITSI-Biosciences leadership have more than 35 combined years of experience in biochemistry, molecular biology and life science research.
- Only the highest quality materials and validated protocols are used at ITSI-Biosciences.
- All laboratory employees are trained extensively before working in the laboratory.
- All equipment used at ITSI-Biosciences are state-of-the-art, and maintained and calibrated regularly.

The report format used at ITSI-Biosciences gives all the important and necessary information to the customer in a concise layout. To ensure a quality report, ITSI-Biosciences uses the following steps:

- Once the testing is finished and results are analyzed, the project manager will prepare the Project Report and submit to the Project Director.
- The Project Director and at least one senior scientist will review the report. Upon approval by the Project Director, the report is sent to the Office Manager for delivery to the customer.
- The Office Manager will attach a cover letter, questionnaire and invoice to the report and send the entire package by email or courier to the customer.
- All reports are marked confidential to protect the intellectual property of the customer.

Related Documents:

200419 - Report SOPs
200415 - Sample Receiving Protocol