Posted on: 05/22/2018 | Edition: 97 | Section: 3 | Page: 1
Body: Ministry of Health / National Health Surveillance Agency

NOTICE OF PUBLIC CALL NO. 2, FROM MAY 21, 2018

The Director-President of the National Sanitary Surveillance Agency, in the use of his duties and having in view of the provisions of art. 54, VII of the Rules of Procedure, approved in accordance with Annex I of Board of Directors - RDC n ° 61, of February 3, 2016, decides to approve and determine the publication of the present external call for proposals for the presentation of proposals by the academic-scientific community, industrial and third sector of experiential studies for ANVISA's servers, in the themes indicated by Agency.

I. Contextualization

ANVISA has several initiatives aimed at bringing together leading scientists and researchers from the country to the process of evaluating health technologies and regulation. Among these initiatives, include: Scientific Committee on Sanitary Surveillance, Technical Chambers (formed by many researchers), formation of partnerships with institutions of reference, promotion of technical scientific events (symposia, scientific panels, workshop, etc.), and others.

In addition, ANVISA also invests consistently in training / training initiatives access to scientific databases, availability of bibliographic material and to offer a consistent set of tools to qualify the institution's decision-making process.

Although the Agency has countless initiatives that seek to support tools and theoretical-conceptual knowledge, the need to policies, practices and challenges faced in the design and development of emerging technologies and innovative. In this sense, the Experiential Studies Program seeks to build another support path scientific technician for decision-making in Sanitary Surveillance, based on the offer of practical experiences with the object to be regulated.

The intention is that the studies be carried out in loco, allowing a practical experience of the regulator with the object under study or, still, by means of another experiential method, that allows the direct contact of the server with the technology studied. With this, an adequate understanding of the design and development of technologies, regulatory impacts and regulatory needs.

It should be emphasized that on-site visits are not intended to inspect, evaluate, judge or perform regulatory function (eg, compliance inspection), but only experiential learning, aiming to add quality to the normative production process and the evaluation of technologies, while helping to ensure consumer confidence in the products and services to be available to the Brazilian population.

II. Two Objectives

Promote a collaborative environment between the Agency, industry, academic-scientific community and sector in the quest to increase the safety and efficacy of products and services to be made available to the Brazilian population;

Gain awareness of existing, emerging and innovative technologies, supporting processes evaluation of technologies and production of regulations in Sanitary Surveillance;

Page 2

Improve critical thinking and problem solving, from a better understanding of difficulties, challenges and regulatory needs in the development cycle of innovative and emerging countries;

Establish transparent and universal criteria and procedures for partnerships with the various actors involved and interested in the evaluation of technologies and production of regulations in Surveillance Sanitary;

III. From the Program Guidelines

The training carried out under the Experiential Studies Program will be based on the following guidelines:

ANVISA will be responsible for the expenses with detachment, stay and food of the servers program participants;

In view of the principle of reasonableness, the usual distance from industries to municipalities, as well as those contained in Technical Note No. 67/2015 / CGNOR / DENOP / SEGEP / MP, can be institutions during the visits, transfers and food service, restricted to the schedule scheduled for the visit;

Except for resources for detachment, stay and feeding, no ANVISA to finance the visits, in whole or in part;

The selection of potential facilities for the technical visits will be based on the priorities of the ANVISA, as well as in the resources available to enable team participation;

The companies participating in the Program must have their situation considered regular by ANVISA, in which refers to the payment of inspection fees for health surveillance;

The news regarding the visits of the ANVISA servers should make explicit reference to the program;

ANVISA will excel in transparency in all stages of the Program (publication of the call, evaluation and selection of proposals).

The servers participating in the visits will sign the Confidentiality Agreement and Sigil, according to the Annex, which will be sent to the partner companies / institutions.

IV. The procedures and conditions for the submission of proposals

The application for participation in the program must be carried out by completing the electronic form until 07/31/2018.

Training proposals must contain the following information:

Theme of interest;

Report on the ability to talk about the chosen topic;

Proposed dates for the visits;

Maximum number of servers to be received;

Agenda containing the schedule of the visit, as well as the topics to be addressed;

Description of the stages of the proposal, structure and professionals that will be part of the programming.

Proposals submitted after the deadline or in disagreement with the terms and conditions established in this call;

Adjustments to the proposals may be agreed for the full understanding of the Agency in themes to be studied.

V. Evaluation and Disclosure of Results

The proposals will be evaluated considering the criteria listed below:

Compatibility of resources needed for training with the availability of ANVISA;

Expertise or pioneering partner in the emerging or innovative technology to be studied;

Regularity of the obligations of the partner with ANVISA;

Page 3

Methodology and proposed programming for the visit.

The proposals will be evaluated by a committee made up of representatives of the Executive Board responsible for theme, by the organizational unit responsible for the theme and by the General Management of Knowledge, Innovation and Research - GGCIP, responsible for the coordination of the Program.

The list of selected proposals will be published in the Anvisa Portal.

SAW. Questions or clarifications

Any doubts or clarifications about the call notice can be directed to the email ggcip@anvisa.gov.br.

VII. Two Themes

In this second edition of the Program of Experiential Studies, proposals will be accepted for study following topics:

Theme 1 - Regulation and Registration of Health Products

1.1 Rigid videoendoscopy electronic systems for surgery, integrated with a surgical high frequency and with laser surgical system (arthroscopy, laparoscopy, surgeries in the digestive system, urinary system, respiratory system, among others) and flexible diagnostic videoendoscopy electronic systems (examples: laryngoscopy, esophagoscopy, rhinoscopy, bronchoscopy, colonoscopy, nasoendoscopy, duodenoscopy, enteroscopy, esophagogastroduodenoscopy, urethrocystoscopy, etc.)

goal of Study: deepen O knowledge technician about operation, integration / compatibility of the parts (modules: image processor, light source, image monitors irrigation module, high-frequency surgical module, Laser Module, among others) and their components and accessories (cables, endoscopes, handles, optics, instrumentals, optical fibers, monopoles, bipolar, trocars, tweezers, scissors, among others). To deepen the knowledge about the main risks and failures of endoscopy systems, interconnection / compatibility failures of the parts and components, as well as the cleaning, disinfection and sterilization procedures recommended by the manufacturer.

Contextualization: Minimally invasive procedures have evolved considerably, and this, thanks to the flexible video-endoscopy electronic systems used for diagnostic purposes and to the rigid surgical videoendoscopy, integrated with a high-frequency surgical laser surgical system. These systems are complex and composed of several modules and dozens of components and accessories, and which are often difficult to understand the operation process, interconnection and compatibility of the parts and components of the system, generating the need for requirements in order to clarify technical doubts.

1.2 Software for diagnosis

Purpose of the Study: to deepen the knowledge about the development of the software having as based on applied quality controls, information security monitoring, version changes, associated risks and market trends.

Contextualization: with the evolution of the technologies applied to the health the software became important part of the products, being used in the integration of digital platforms, in the of dignified results and often being the product itself. Given the wide applicability of software and the different users (laypeople, patients, health professionals) and issues related to access, sanitary authorities discuss definitions applicable to health worldwide, structure for the categorization of software risk, the quality monitoring system and the best design for clinical evaluation, with the purpose of guaranteeing safety and efficacy in the use of this type of product. Anvisa has the theme as part of the Regulatory Agenda and currently includes products under the responsibility of two managements - Equipment Technology - GQUIP and Product Management for in vitro Diagnostics - GEVIT.

Reference: Regulatory Agenda - Regularization of software as a medical device (8.5)

1.3 Nanotechnology in materials used in health

Page 4

Aim of the Study: The study of the incorporation of nanotechnology in materials of use in health has to provide Anvisa's technical staff with an opportunity to explore the various applications technology and possible influences on the safety and efficacy of these products.

Contextualization: nanotechnology is a technology that allows the use of particles at scale nanometric properties in a given product, thus allowing properties different from those provided by larger particles. The use of this technology has increased in several branches including health, such as for example, use in medicines, cosmetics and materials for health use. In relation to the materials used in health, we can cite the following application examples: use in implant coverings (vascular stents, orthopedic and dental implants) in order to increase biocompatibility; use in bandages and screens with the aim of promoting antimicrobial activity; use of nanomaterials to mimic body structures to optimize the biological, physical and mechanical properties of implants; among others.

However, this new technology creates challenges for health regulation, especially in guarantee the control and mitigation of the possible risks posed by these particles and the demonstration of the actual alleged effects of more effective use of the product in a given clinical context.

Topic 2 - Regulation of Blood, Tissues, Cells and Organs

2.1 Advanced Therapies Products

Purpose of the study: visit to development environments or production of Therapy Products Advanced, providing a practical experience of the regulator with the object of study - main focus on Gene Therapy Product consisting of or based on cells.

Contextualization: Products of Advanced Therapies represent a therapeutic possibility in complex clinical situations and without available medical alternatives. These new technologies challenges to the development of regulatory mechanisms related to their production and characterization, to conduction of clinical trials and the determination of safety requirements, quality and evidence of efficacy for its registration, distribution and use.

Advanced Therapy Products are those that have been subjected to extensive manipulation in laboratory, such as expansion and differentiation of cells in culture or modification of their genetic material and also sometimes perform a different function from that of the original organism. These products are classified as:

1. advanced cell therapy products: if they consist of human cells or their derivatives, they do not chemically defined;

2. tissue engineering products: consisting of human cells organized in tissues or tissues; in the presence or absence of structural support consisting of biological or biocompatible material; and

3. gene therapy products consisting of or based on cells: if obtained by means of transfer of genetic material (DNA, RNA or oligonucleotides) into human cells.

The production of an Advanced Therapy Product presents a number of critical points which, if not properly monitored, will result in a risk to the health of the user. Some of these risks variability and complexity inherent in the components used in the elaboration of the final product, such as the variable source of cells, the degree of purity of the materials used, the potential for contamination by agents of the donor, the production process itself (in particular, expansion and differentiation of cell) that may alter the biological characteristics of the cell, contamination by microorganisms present in the environment and the inability to sterilize the final product. The distribution of these products also can be a great challenge due to the characteristics of fragility and short term of validity of the products fresh (not frozen). Therefore, these products must be properly regulated so that the risks involved in its production and clinical use are minimized.

With this objective, Anvisa is developing the regulatory framework for Therapeutic Products Advanced, based on:

Page 5

1. in the pre-market evaluation of these products, that is, in the implementation of control mechanisms developmental stages (clinical trials);

2. in the implementation of Good Practices for producing establishments; and

3. the availability of the products in the national territory through sanitary registration.

Reference: Regulatory Agenda - Advanced Therapy Products: Advanced Cell Therapy, tissue engineering and cell-based gene therapy (10.4).

2.2 Blood establishments Human Plasma suppliers for industrial fractionation

Aim of the Study: to know the processes of production of blood products and to identify the control mechanisms adopted for the fractionation industry and plasma accordance with the local Regulatory Authority, in relation to the Good Practices applied to the blood cycle.

Contextualization: The World Health Organization (WHO) recognizes blood and its components as essential medicines for national health-care systems, and recommends that countries development of institutionally established regulatory systems, with surveillance of blood products and services, which are considered to be highly vigilant.

Anvisa, adopting WHO conceptual, recognizes that blood and blood components are products biological purposes for therapeutic purposes but which, by their very nature, are exempt from sanitary registration. This In this way, it is essential to apply the Good Manufacturing Practices (GMP) in the production cycle of blood to meet the safety and efficacy requirements of these products.

It is possible to affirm that the politics and the regulation of blood in Brazil has evolved significantly in the technical standards have become more stringent, based on the principles of GMP and that both hemotherapy services have been seeking excellence, and the the plasma fractionation industry for the production of blood products. In addition, regulatory mechanisms have been improved, for example, with the systematization of procedures and the training of inspectors in BPF in the blood cycle. Currently, the Management of Blood, Tissues, Cells and Organs - GSTCO / Anvisa provides, among its strategic objectives, the development of mechanisms for induction good practices in establishments that process blood, with the perspective of certification of establishments (hemotherapy services) plasma suppliers for the blood products industry.

Finally, one scenario to be considered is the expectation of transfer of technology, from the the efforts of the Brazilian Ministry of Health and the Brazilian Hemoderivative and Biotechnology Company - Hemobras, aiming at to the production of blood products by the national industry. This advance, which is expected in the coming years, should also be accompanied by agile and effective regulatory mechanisms, based on best practices and aligning Brazilian regulation in the context of regulatory convergence and strengthening reliance.

In this way, the experience in consolidated international models as well as the exploration of new Regulatory trends should support Anvisa's assessment of the introduction of regulatory not implemented in the country for the area of blood and blood products, which should meet the needs of of the technological park that has been developed in Brazil, enabling cooperation and trade but also enabling innovation, improvement and simplification of processes, with a focus on the efficiency and health risk management.

Topic 3 - Regulation and Registration of Food Products

3.1 Manufacture of Formulas for Inborn Metabolism Errors

Purpose of the Study: To know the specificities of the productive processes of formulas for errors and identify critical control points, in order to support the to review the regulatory framework for the regularization of products with SNVS.

Contextualization: Formulas for inborn errors of metabolism are currently classified in the category of Special Purpose Foods. They are intended for the feeding of people with phenylketonuria.

Phenylketonuria is a genetic disease, identified by the accumulation of phenylalanine due to the defect or absence of the enzyme hydroxylase.

Patients with the disease can not metabolize phenylalanine, which accumulates in the blood and is converted into toxic compounds, such as pyruvic acid. This acid can affect the neurological system.

Currently the formulas for inborn errors of metabolism are exempted from sanitary registration.

Given the vulnerability of people who use this type of product, Anvisa studies the possibility to amend the regulations with a view to establishing technical requirements proportionate to the health risk of associated with the use of the product.

Reference: Regulatory Agenda - Procedures for regularization of food and packaging (4.1) and Sanitary Requirements for Special Purpose Foods (4.13).

3.2 Manufacture of extracts and concentrates, of vegetable origin, for use as colors and flavorings

Aim of the Study: To know the specificities of the productive processes of vegetal extracts and vegetable concentrates intended for use as flavorings with a view to subsidizing the technical analyzes and requirements to be established for the inclusion or extension of the use of coloring and flavoring additives from concentrated plant extracts.

Contextualization: Coloring and flavoring additives from vegetable extracts and concentrates regulated by the Resolution of the Collegiate Board of Directors - RDC No. 2 of January 15, 2007, which internalize the decision in Mercosur and approve the technical regulation on flavoring additives. With regards to botanical species, there is the provision of temporary acceptance for use in certain beverages and foodstuffs, plants and / or parts thereof that have a long history of consumption without evidence of adverse effects the specific technical requirements.

By means of Normative Instruction n. 15 of April 13, 2017, the procedures for the evaluation of flavoring additives from regional botanical species.

The technical visits to the manufacturing companies will provide further technical knowledge regarding the production processes, the applicable quality control tests, the determination of technical specifications and standardization of vegetable extracts to be used as additives dyes and food flavorings.

Knowledge of the production process of vegetable concentrates may also help the area in the decision matrices for framing these vegetable concentrates as additives, novel ingredients, bioactive substances or common ingredient.

Reference: Regulatory Agenda - Health requirements for food additives and food additives technology (4.4).

Theme 4 - Regulation of Agrochemicals

4.1 Occupational risk - scenarios and technologies for the application of agrochemicals

Purpose of the study: to promote the field experience to regulators in the field of application of agrochemicals in an agricultural production environment, in order to facilitate the identification of exposure of operators and re-entry workers involved in activities related to the use of these products, in order to carry out the occupational risk assessment.

Contextualization: Due to the absence of exposure data in Brazil, the risk assessment can be achieved using international generic databases such as (PHED - Pesticide Handler Exposure Database and AHETF - Agricultural Handler Exposure Task Force) or European (AOEM - Agricultural Operator Exposure Model). These models present exposure in the different tasks contemplated in the use of pesticides: Mixture and Supply and Application. However, it is possible that not all the scenarios presented in these models can be applied to the Brazilian conditions, considering, among other factors, the differences in Good Agricultural Practices, equipment, crops, seed treatment techniques, etc. In order to assess the applicability of each model to the Brazilian conditions it becomes necessary to know the field reality, involving from the preparation and supply of the product for use until its application, with emphasis on the differentiation of various cultures and the different types of equipment used to apply different classes of pesticides.

Page 7

With the publication of Public Consultation No. 485/2018, which establishes the criteria for risk assessment occupational, it is necessary to establish the methodology and parameters to be adopted for this evaluation, so that experiencing the field activities will help in the correct identification of the scenarios, in the correlation with the available international data and the identification of limitations for subsequent

development of studies in the country. As a consequence, it will be possible to carry out a risk assessment with a better technical-scientific basis, resulting in a correct recommendation of personal protective equipment for the protection of the health of the worker involved in the different activities related to the use of agrochemicals in Brazil.

Reference: Regulatory Agenda - Occupational and dietary risk assessment of agrochemicals (3.5)

Theme 5 - Regulation of Technologies in Health Services

5.1 Technologies and materials for use in health services

Purpose of the Study: to know the design and manufacturing process of technologies that have prevention and control of health care-related infections, such as catheter peripheral, central venous catheter, catheter of hemodynamics, equipment, probes enteral, nasoenteral, bladder, respiratory filters, bacterial filters, dressings, dialysers, dialysis lines, surgical and procedures, prohibited processing products, low / high speed rotary dentistry, sterilization equipment, products manufactured with new technologies for IRAS prevention (sterile and antiseptic dressings, antiseptic devices), as well as means of general use cultures in microbiology laboratory, blood culture bottles, different equipment currently used in the microbiology laboratory (automation). Also to know the vision of the regulated entity regarding the health regulations.

Contextualization: health care-related infections (IRAS) are associated with quality of health care. It is a serious public health problem and morbidity and mortality of hospitalization time. It becomes even more serious with the occurrence of resistance microbial (RM). There are a number of IRAS and MRI prevention and control measures and some of them involve the use of technologies and products for health that favor the quality of care and consequently the reduction of infections and patient safety. Given this, the visit to manufacturing industries of these technologies will broaden the knowledge horizon of the general management technicians in order to subsidize proposing preventive and control actions, as well as the evaluation of health services.

Reference: Regulatory Agenda - Good Practices for the management of technologies in Cheers.

5.2 Product reprocessing services

Aim of the Study: the knowledge and visits to Process Institutions and Materials Centers and Sterilization of Health Services has the purpose of providing the regulator with the practical knowledge of new technologies for cleaning, disinfecting and sterilizing products, of the validations adopted in the health products, as well as the feasibility of validation of processing of products, in order to contribute to the improvement of existing health requirements.

Contextualization: the processing of health products comprises the set of actions related to pre-cleaning, receiving, cleaning, drying, integrity and functional evaluation, preparation, disinfection or sterilization, storage and distribution, as well as interrelated processes for ensure the safe reuse of products used in support of diagnosis and therapy. In this way, Anvisa has mechanisms to improve the requirements for these steps in order to sanitary safety of the processes in Material and Sterilization Centers and Processing Companies. Thus, the practical knowledge and visit to these establishments aims to add value to the processes of Anvisa's Regulatory Agenda, in order to contribute to existing standards. Another interesting approach is the observation about the context of the Validation practices of Protocols-Test for the processing of products, overcoat products included as Single Use

processing, in Brazilian or international reality. In this way, it is important to understand the policies adopted by Processing Companies and Health Services, the technical criteria and practices of validation of processing steps for this type of product, which represents a major challenge to the regulation of products and services. Another issue concerns the latest cleaning and sterilization of products that have been developed, with the relative absence of standardized parameters on the validation of certain processes, especially sterilization at low temperature and its incorporation in the Brazilian reality, which represent another important challenge with regard to the guarantee of the

quality of these processes and the effective performance of the National Health Surveillance System.

Reference: Regulatory Agenda - Good practices for the processing of health products.

Topic 6 - Monitoring of Products Subject to Sanitary Surveillance

6.1 Cosmetology Surveillance

Purpose of the Study: To provide Anvisa's technical staff with practical experience on the functioning of the cosmetovigilance system implemented, giving an opportunity to visualize the entire flow of work, from abstraction, evaluation of adverse effects or other problems reported by the consumer, related to the use of the cosmetic product, and therefore the corrective measures adopted to minimization and elimination of risk, if appropriate.

Contextualization: Cosmetovigilance is a system that allows to observe which problems identified when the product is made available to the market and on a large scale, it is the monitoring of the post-market / use products, proving to be a very important and to the manufacturer of the product, which will receive directly from the consumer eventual problems with normal use product, giving the opportunity to improve the quality of the product, as well as to the regulator, as it allows the strengthening of post-market monitoring and regulation activities. By simplifying registration, that is to say, release of the products on the market more automatically, without prior data, a challenge was created for sanitary regulation, which will have to act more incisively in trade, monitoring the products, promoting better control of these products and, therefore, have the ability to minimize or eliminate potential risks related to the use of the product, together with the manufacturing company.

Topic 7 - Management of Information on Emergencies in Sanitary Surveillance

7.1 Systems, procedures, methods and technology resources for mapping threats and vulnerabilities to disasters that may impact the availability of products and services subject to health surveillance.

Purpose of the Study: to identify the systems, procedures, methods and technological resources aimed at (i) mapping threats and vulnerabilities to disasters that may impact access, (ii) evaluation and management of this type of risk, (iii) assessment of the impact of the damage and (iv) quick alternatives recovery of businesses and installations of products and services regulated by sanitary surveillance.

Contextualization: the emergency of public health caused by disaster is a serious interruption of the functioning of a community causing deaths and significant material or environmental losses, which exceed the capacity of the affected community to deal with the situation. The effects of disasters can be days, weeks or months after their occurrence and seriously affect products and services regulated by sanitary surveillance, which, in addition to economic losses, contributes to aggravate even more the health condition of the affected population.

These damages may also reach a national dimension as a result of the interruption of damage to roads which, in addition to preventing worker access, may compromise quality of air and water, causing damage to the replacement of health technologies. They are also capable of the economy of several municipalities simultaneously, giving rise to a scenario of orders

Page 9

Since January 2018, the Health Information Management Coordination Public Health Emergencies (CVISA / DSNVS-Anvisa), has been implementing a set of projects to institutional purpose of coordinating timely preparedness and response public health emergencies, involving risks to the availability of products and services regulated by surveillance, through intra-agency and inter-agency actions.

One of the areas of activity in the area is the preparation and response of health surveillance (VISA) for the facing disasters. On this front, a National Guide is being developed to guide the of the National Health Surveillance System on the potential for unavailability of products and services managers in decision-making on the need to develop or

preparedness and response plans and in order to support establishments in the preparation, management and reestablishment. On another front, it involves the operationalization, from the preparation to the reconstruction, a consistent and harmonized strategy for vulnerability mapping, assessment and management of risks, as well as monitoring the impact of the damages resulting from this type of event. And, finally, another of CVISA is the creation of a National Network for the purpose of monitoring the availability of pharmaceutical technologies, whose initial composition is of health professionals who work in the technical responsibility of transporters, Central Pharmaceutical Supply, Distributors, Pharmacies and Drugstores and health services.

Finally, learning of health surveillance from experiential models of the productive sector, enables the identification of initiatives with some degree of validation, reducing the time between the stages of studies, development and implementation, as well as strengthening the principles and activities disaster management, such as coordination and integration.

JARBAS BARBOSA DA SILVA JR.

ANNEX - TERM OF COMMITMENT FOR CONFIDENTIALITY AND SECURITY

IDENTIFICATION
Name:
Office:
SIAPE:
Institution: National Health Surveillance Agency - Anvisa
Bus:
Company visited:
Date of visits:

The Program of Experiential Studies, launched through the Call for External 2 / ANVISA, dated 05/21/2018, aims to allow an experiment of the regulator with the object of study, thus enabling an adequate understanding of the design and development practices of the technologies, impacts and regulatory needs.

On-site visits are not intended to inspect, evaluate, judge or perform a (eg, compliance inspection), but only a learning opportunity experiential, aiming to add quality to the process of normative production and technology evaluation.

In summary, the on-site visits have the following objectives:

5. Promote a collaborative environment between the Agency, industry, academic community and institutions seeking to increase the safety and efficacy of products and services to be available to the Brazilian population;

5. Raise awareness of existing, emerging and innovative technologies by subsidizing processes of evaluation of technologies and production of regulations in Health Surveillance;

5. Improve critical thinking and problem solving, based on a better understanding of the difficulties, challenges and regulatory needs in the development cycle of innovative and emerging markets.

Aware of the objectives of the Experiential Studies Program, I am committed to confidentiality and safeguarding the secrecy of all the information made available by the company / institution ..... during the visits of the Experimental Studies.

I hereby declare that I am aware of and undertake to ensure that the information received as a result of Program of Experiential Studies should be used only for the purpose of well and faithfully complying with objectives and attributions of the Program, and its disclosure to third parties is prohibited without prior and express consent of the company / institution visited.

I am aware that it is not permitted to produce copies or backup, by any means or form,

any of the documents furnished to me or which have come to my attention by virtue of of visits.

I understand that I must disable electronic files, as well as any

has been made available and which contains confidential information, where it is no longer

be kept under my guard, and I undertake not to retain any

any means or form.

Finally, I am aware that I can not make sensitive documents and information available

guarded by Anvisa, as well as to maintain conduct that causes any kind of favor to third parties.

I hereby declare that the information provided herein is true

Place and date:

_____

signature