International Colloquium on

Biotechnology & Industrial Revolution

June 12-13, 2018. Paris France

bioteksa®
Inteligencia que Nutre

Zimmer & Peacock
eSensor Manufacturing and Technology

AEM Biotech 2018

Conference Souvenir

ABOUT AEM:

AEM- Give Life to Your Research

It's great to share the knowledge and experience of world business leaders and research scientists in face to face meetings and personal interactions. At AEM Events, you can stimulate your brain via exploration of creative ideas with leaders in your field. Our conferences focus on research, business strategies, current innovation and developments, rapid business development approaches and high-class networking. At AEM Doors were open to worldwide interactions and global business through scientific presentations and commercial exhibitions.

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One from Best Leading Companies:

Leading Companies we observed and recommended from our end are comes under this category, every year we recommend a single company, which is doing their global business and growing very rapidly in the market with their quality, activity and good name with cost effective products. This Year we found Bioteksa.

In their words…

(Bioteksa) www.bioteksa.com

Business Model:

We are different We do it better-

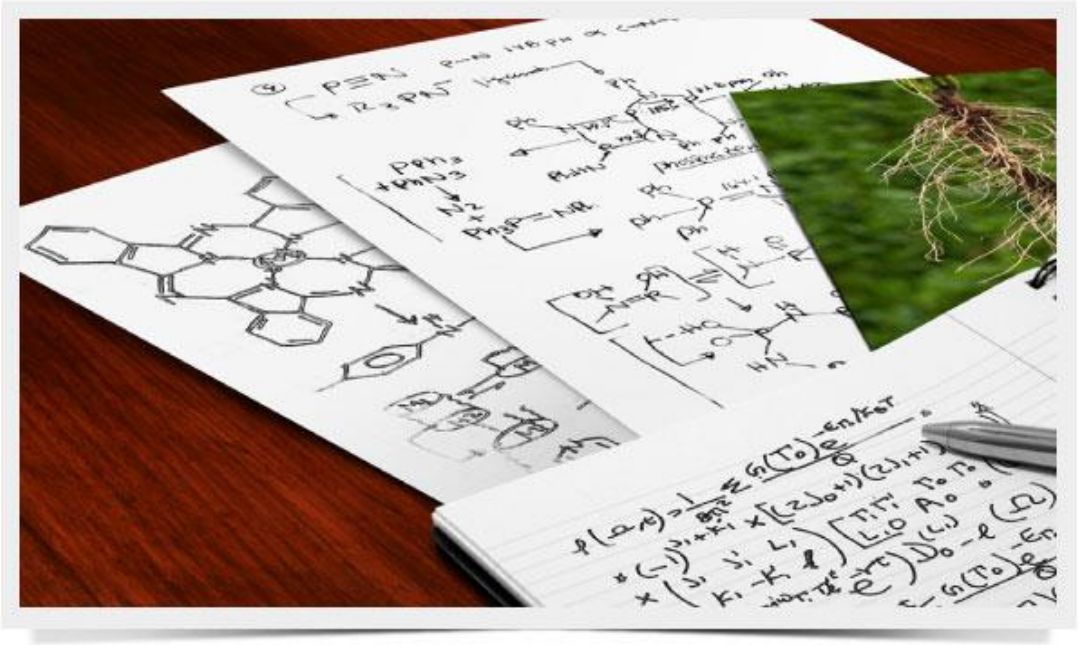
The inadequate use of natural resources and the alarming deterioration and low yield of the cultivated soils require Intelligent Solutions that allow the agricultural producers to achieve crops with significant yields, that also respond to the strategic demands of the local, regional, national markets and worldwide.

BIOTEKSA ® is a company founded in Ciudad Jiménez, Chihuahua, Mexico, which with a scientific-business focus, constantly seeks the "state of the art" in all its areas and disciplines. Our great added value is the generation of scientific ideas that result in the design and development of state-of-the-art plant nutrition technology, applying the most advanced scientific models that today position BIOTEKSA ® as one of the most innovative companies in the world. creation of unique products and methodologies with outstanding results in terms of plant nutrition, health, traceability, certification in crop management and vegetable overproduction.

The great advantages that you obtain in each of the products of Colloidal Nutrition Amfífila Enantiomórfica ® and field solutions, are the application of a purified scientific thought that provides the broad confidence and security to nourish your crops with the highest quality and efficiency available in the market.

Mission:

Develop scientific knowledge for the benefit of plant nutrition and the food of humanity.



Food is currently one of the great issues of humanity in the present and certainly in the immediate future. The global overpopulation and growth prospects require serious and timely attention to this great problem that has a very close relationship with the ecological and sustainable fragility in which our planet lives.

At BIOTEKSA ® we are aware of the overexploitation of productive soils in all regions, the scarcity of healthy irrigation water and environmental pollution. For this reason, our company has a unique scientific model in the world, Scientific Model Lightbourn ® that with great viability and assertiveness is contributing to achieve the best vegetable nutrition, taking care of the environment of the plant in an integral way, maximizing the performance of crops and our customers' business.

Biotechnology:

The Lightbourn ® Biochemical Model

and Lightbourn ® Metabolic Engineering

Created by Dr. Luis Alberto Lightbourn Rojas, the Biochemical Model Lightbourn ® traces through mathematical models the intelligent interaction that exists between the Soil-Water-Plant-Environment system and the impact of each and every one of the nutrients in the various phenological stages, both vegetative and development, of the crop.

This allows BIOTEKSA ®, through the application of Metabolic Engineering Lightbourn ®, to create exclusive designs of nutrient molecules perfectly compatible with the nature of the formation of ion channels of plant cells and stomata of leaf surfaces. Nutrients that achieve the most effective and perfect income through a natural transporter: the colloid (fifth essence of matter) with unique characteristics of amphiphile (unique feature to retain and release water) and enantiomorphy (physical morph capacity adaptable to various forms radicular and foliar of the plants).

Working at scales Nano-one millionth of a millimetre-and Femto-one millionth of a nanometre- is what makes the difference and makes us better, since our biotechnology focuses on not damaging and not hindering. This is why only BIOTEKSA ® nourishes with maximum compatibility according to the complex physiological nature of the plant.

Bio Synergy Colloidal NFT ® -Nano Femto Tecnológica-

The future of plant overproduction

The technology of Bio Colloidal Synergy NFT ® works in a manner compatible with the nature of the plant, boosting its energy factors naturally, allowing all the energy generated by it to be used in the processes of growth and vegetative consolidation and development, achieving thus a better use of economic resources in the total management of the crop cycle.

The nutrition mechanisms of BIOTEKSA ® NFT ® Colloidal Bio Synergy make the natural genetic expression of plants manifest 100%, regardless of the type or genre of the crop.

The agrological producer can verify in days and even hours its high nutritional effectiveness, both edaphic and foliar; it significantly elevates key performance factors such as better rooting, turgor, leaf area development, flowering, sprouting, size and filling, intrinsic issues of great importance in production.

Colloids Enantiomórficos Amfífilos ® . The most advanced biotechnology to nourish vegetables with the greatest effectiveness and without waste

High biotechnology packaged so that your agrological business can earn more

A company of World Quality

- **BIOTEKSA ® is a company aware of the importance of having the highest quality standards worldwide that certify not only the quality of our products, but also the quality of our production processes as well as the verification of our methods, developments and research. scientific That's why we count on the safety and confidence of our clients with the following certifications:**

Products:

Two Exclusive Lines 1) NUBIOTEK ® ULTRA, 2) NUBIOTEK ® HYPER

1) NUBIOTEK ® ULTRA

NUBIOTEK® ULTRA Ca

NUBIOTEK® ULTRA HBK

NUBIOTEK® ULTRA K

NUBIOTEK® ULTRA Mg

NUBIOTEK® ULTRA N

NUBIOTEK® ULTRA NPK

NUBIOTEK® ULTRA P

NUBIOTEK® ULTRA SN

2) NUBIOTEK ® HYPER

NUBIOTEK® HYPER BMo

NUBIOTEK® HYPER CaB

NUBIOTEK® FBK

NUBIOTEK® HYPER Fe+Mg

NUBIOTEK® HYPER K

NUBIOTEK® HYPER OXY

NUBIOTEK® RFZ

NUBIOTEK® HYPER Zn

http://www.bioteksa.com/productos/index.php

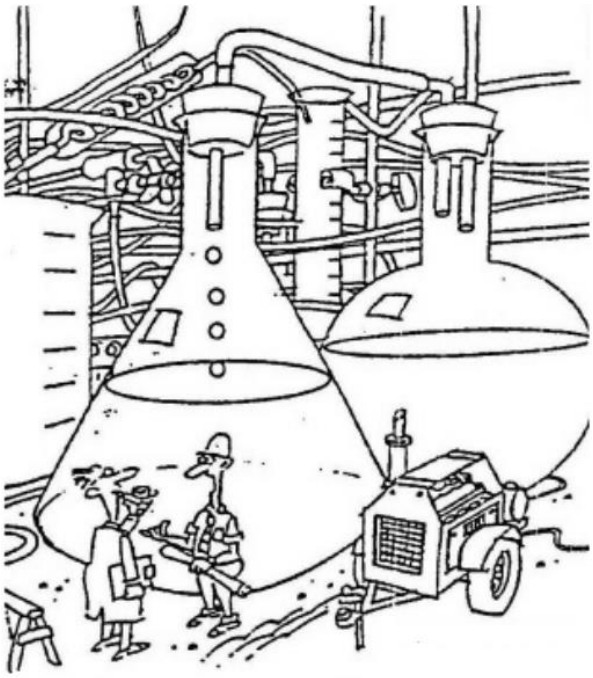
Program

International Colloquium on Vaccines & Immunology

June 12, 2018		
Conference Agenda		
Morning Sessions		
	Time	Schedule
	10.00-10.15	Inaugural Address
Bertrand Lagarde, ITG Consulting, France	10.16-11.00	Scaling down to better scale-up: a mind shift in r&d labs….
Certification	By, Luis Alberto Lightbourn Rojas, Bioteksa	
Coffee Break	11.00-11.15	Group photo/Panel Discursion
Luis Alberto Lightbourn Rojas, Director, Bioteksa, Germany	11.16-12.00	Critical role of G protein signaling in responses to environmental change: protection from UV radiation damage in plants
Certification	By, Bertrand Lagarde, ITG Consulting	
Won-Gon Kim, Korea Research Institute of Bioscience and Biotechnology Korea.	12.01-12.45	New potent anti-Gram-negative compounds from the myxobacteria Corallococcus coralloides
Certification	By, Bassam Tarablsi, Sup' Biotech	
Bassam Tarablsi, Sup Biotech, France	12.46- 01.30	Bioplast'Oil, from oil to bioplastic
Certification	By, Won-Gon Kim, Korea Research Institute of Bioscience and Biotechnology	
Break	01.31-02.30	Networking
Houman Moteshareie, Carleton University, Canada	02.31- 03.00	Sensitivity of yeast gene deletion strains for ITT1 and RPS1A to arsenite connects their activities to the expression of URE2, a key gene involved in metal detoxification
Certification	By, Bassam Tarablsi, Sup' Biotech	
Delegate/Host Certification	By, Bassam Tarablsi and Houman Moteshareie	
Concluded		

Scaling down to better scale-up: a mind shift in R&D labs….

Bertrand Lagarde, ITG Consulting. France



More than 90% of the R&D bench top jobs, designed to be scaled-up, are aborted due the lack of consideration in choosing the right tools to elaborate and validate the recipes.

Indeed, vessels, agitation, heat exchanges, centrifugation, filtration, ultrafiltration and many more laboratory applications, do **NOT** find their equivalent for a reliable scale-up from the very first steps of designing a pilot, an industrial demonstrator or a full-scale production plant.

On a technical side, this leads to a waste of time in re-designing every single step of each individual processes, with the need of re-validating each of them, and ultimately crossing fingers that putting them back together will finally deliver the expected results found after bench-top jobs.

On the Financial side, if some of the scale-up have been successful, the Operational Expenditure (OPEX) could become far from what was initially expected and the final cost of your molecule of interest could becoming very wrong.

Based on a 30+ years' experience and expertise, I can provide you with a new approach to save time (and money) in order to streamline the scale-up process, from the very first steps of R&D to lab pilot, to industrial demonstrator and finally to full scale production.

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Critical role of G protein signaling in responses to environmental change: protection from UV radiation damage in plants

Luis Alberto Lightbourn Rojas, Instituto de Investigación Lightbourn, A. C. Bioteksa

Abstract

Abiotic factors that cause stress in plants included extreme temperatures, drought, nutrients, salinity and radiation. Plants are vulnerable to UV-B radiation, because their needs sunlight to survive. UV-B affects growth, morphology and physiology of plants. This damage that can see at physiological level is related to differential gene expression induced by UV-B. Therefore, the identification of genes related to the to the response to UV-B stress, provide knowledge about the molecular mechanisms through which plants can avoid damage cause by UV-B radiation.

The dates indicate that the plants G protein-signalling pathway is critical to providing protection from UV-radiation, and does so via the activation of PD1, resulting in the synthesis of phenylalanine. G-proteins perceive the extracellular environment through receptors on the plasma membrane transmitting signals to signaling molecules inside the cells known as effectors.

In this study, the UV regulation of a simple signaling pathway in *Capsicum*, G protein signaling in UV protection and acclimation early in development, is investigated with the use of the transcriptome analysis to identify the differentially expressed genes involved in the UV-B stress response of the plant. This study is important for characterization of biological markers to plant protection against environment stress and the agricultural production improvement of this crop.

Biography

Dr. Luis Lightbourn has a bachelor's degree in Chemistry and PhD in Molecular Biology graduated Summa Cum Laude. Lightbourn is civil scientific and entrepreneur researcher co-founded of the research institute "LIGHTBOURN RESEARCH" and "BIOTEKSA" an agribusiness solutions company. His expertise is in the interface of chemistry and biology pertaining to nanomaterial. The research interest of Lightbourn Rojas is focused broadly on science and technology at the nanoscale and for material science to push scientific boundaries in diverse areas of chemistry, biochemistry and bionanofemtotechnology. He has also been actively involved in enhancing the societal awareness of food biotechnology issues around the world.

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New potent anti-Gram negative compounds from the myxobacteria *Corallococcus coralloides*

Won Gon Kim, Korea Research Institute of Bioscience and Biotechnology, Korea

Abstract:

Recently, infections caused by MDR Gram-negative bacteria have become a growing problem. There is an urgent need for new agents to treat infections caused by Gram-negative bacteria resistant to currently available agents. Myxobacteria are a group of Gram-negative bacteria that produce a diverse range of bioactive secondary metabolites. Myxobacteria have received attention as a source of novel anti-infective natural products. Our objective is to search for anti-Gram-negative metabolites from Korean myxobacteria. Two new potent anti-Gram negative compounds, coralmycins A (1) and B (2), were isolated from cultures of the myxobacteria *Corallococcus coralloides* M23, together with another derivative (3) that was identified as the very recently reported cystobactamid 919-2. Their structures including the relative stereochemistry were elucidated by interpretation of spectroscopic, optical rotation, and CD data. The antibacterial activity of **1** was most potent against Gram-negative pathogens, including *Escherichia coli*, *Pseudomonas aeruginosa*, *Acinetobacter baumanii*, and *Klebsiella pneumoniae*, with MICs of 0.1–4 μg/mL; these MICs were 4–10 and 40–100 times stronger than the antibacterial activities of 3 and 2, respectively. This result suggested that the β-methoxyasparagine unit and the hydroxy group of the benzoic acid unit were critical for antibacterial activity. Thus, this study indicated that **c**oralmycin A has great potential for treatment of multidrug-resistant bacteria, including Gram-negative bacteria.

Biography:

Won Gon Kim has completed his PhD at the age of 32 years from Seoul National University, South Korea, and postdoctoral studies from NIH, USA. He is a principal research scientist of Korea Research Institute of Bioscience and Biotechnology (KRIBB), South Korea. He has published more than 90 SCI papers in reputed journals.

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Bioplast'Oil, from oil to bioplastic

Dr. Bassam Tarablsi, Sup' bitech, France

Abstract Description:

Every year, 80 thousand tons of used food oil are produced in France. Only 25% of those are collected. The other 75 percent have dire consequences on the environment: sewer and purification plants obstruction, asphyxiation of watercourses, large CO2 emissions. The collection of these used oils are a legislative obligation. The need to find an alternative to current recycling methods is a priority. Currently, no entirely green solution has been developed.

This is the aim of Bioplast'Oil: a process respectful of the environment, part of a circular economy and a sustainable development. This initiative aims at transforming this pollutant into bioplastic, using the metabolism of a bacteria. The bioplastic produced could have application in the packaging industry for example.

The technique relies on a unique media formulation for bacterial growth supplemented with fried oil as a unique carbon source. The bio-disponibility of substrate is maximized to attain the highest yield for this polymer, produced naturally by our bacterial strain.

By proposing a smart and entirely green transformation, Bioplast'Oil would be the first to enter this kind of market. Although some industries like methanisation processes and biofuels are developed, those still produce pollutants.

*Corresponding Author's Biography:

Dr. Bassam Tarablsi started his formation at the University Grenoble I where he got a master degree in Polymers for advanced technologies. He then wrote his PhD on the chemistry of materials at the University of Haute-Alsace-Mulhouse-Colmar from 2005 to 2008. His post-doctoral work was done on the processes of photopolymerisation in emulsion in photoreacteurs. Dr. Tarablsi is now a researcher and lecturer at Sup'Biotech, school of engineering in biotechnologies, and at the University of Rouen.

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Sensitivity of yeast gene deletion strains for ITT1 and RPS1A to arsenite connects their activities to the expression of URE2, a key gene involved in metal detoxification

Houman Moteshareie, Carleton University, Canada, Ottawa

Abstract

Heavy metal and metalloid contaminations are among the most concerning pollutions in the environment. Consequently, investigating the molecular mechanisms that drive the detoxification pathways in living organisms is of importance. To date, a variety of genes have been reported to play a role in the detoxification process. The expression of these genes can be controlled at both transcriptional and translational levels. In baker's yeast, *Saccharomyces cerevisiae*, resistance to a wide range of toxic metals is regulated by glutathione S-transferase products. Yeast URE2 protein has glutathione peroxidase activity and is homologous to mammalian glutathione S-transferases. Its expression is critical to cell survival under heavy metal stress. Here, we report on the finding of two genes, *ITT1*, inhibitor of translation termination, and *RPS1A*, ribosomal protein 10 whose deletion strains exhibit similar drug sensitivity phenotypes to gene deletion strain for *URE2*. Neither of these genes was previously linked to metal toxicity. Our gene expression analysis illustrates that these two genes affect *URE2* mRNA expression at the translational level.

Biography:

Houman Moteshareie is a yeast geneticist (1980-) who made a number of successful investigations in translational pathways and heavy metal toxicity in yeast. He also is a member of Carleton Bioinformatics Group and their research led to the development of an accurate computational algorithm (PIPE) to predict protein-protein interactions. This research eventually led to the development of another algorithm to design novel proteins to interact with a given target protein and avoid interacting with non-targets. Houman's investigation using yeast *saccharomyces cerevisiae* as a model organism, led to a number of publications during his PhD investigation in Canada, Ottawa.

Can Ag-Biotechnology Be Part of Sustainable Agriculture?

Dr. Benjamin Kaufman, Independent consultant, France

Abstract

Merriam Webster dictionary defines biotechnology as: the manipulation of living organisms or their components to produce useful usually commercial products. Sustainable agriculture aims to integrate: a healthy environment, economic profitability, and social and economic equity at present and future generations. The ideas at the base of biotechnology and sustainability do not have any intrinsic dichotomy, but in many eyes, they are mutually exclusive ideas and practices, especially when considering the perception of many that equates biotechnology with genetic engendering and genetically modified crops. This presentation will concentrate on various sustainable agriculture practices as they pertain to soil management, crop management, water management, disease/pest management and waste management, will examine the interrelations with, or the impact of, relevant current and developing biotechnology, and will discuss their present and future compatibility.

Biography

Dr. Benjamin Kaufman, educated in the fields of population genetics (MSc. Tel-Aviv University) and molecular genetics (PhD, University of Illinois), served as the Secretary General for the International Seed Testing Association, and as a Senior Research Scientist at DuPont Pioneer. Dr. Kaufman pioneered developing methods for GMO testing and disseminating testing capacity worldwide, is an expert in molecular marker systems and their use in agricultural biotechnology applications. Presently Dr. Kaufman serves as independent consultant to the seed industry on topics of quality assurance and genomic interrogations.

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Fungi and biodegradation of plastic

Sehroon Khan

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World Agroforestry Centre, East and Central Asia, 132 Lanhei Rd, Heilongtan, Kunming 650201, Yunnan, China

Abstract

The xenobiotic nature and lack of degradability of polymeric materials has resulted in vast levels of environmental pollution and numerous health hazards. Different strategies have been developed and still more research is being in progress to reduce the impact of these polymeric materials. This work aimed to isolate and characterize polyester polyurethane (PU) degrading fungi from the soil of a general city waste disposal site in Islamabad, Pakistan. A novel PU degrading fungus was isolated from soil and identified as *Aspergillus tubingensis* on the basis of colony morphology, macro- and micro-morphology, molecular and phylogenetic analyses. The PU degrading ability of the fungus was tested in three different ways in the presence of 2% glucose: (a) on SDA agar plate, (b) in liquid MSM, and (c) after burial in soil. Our results indicated that this strain of *A. tubingensis* was capable of degrading PU. Using scanning electron microscopy (SEM), we were able to visually confirm that the mycelium of *A. tubingensis* colonized the PU material, causing surface degradation and scarring. The formation or breakage of chemical bonds during the biodegradation process of PU was confirmed using Attenuated Total Reflectance Fourier Transform Infrared (ATR-FTIR) spectroscopy. The biodegradation of PU was higher when plate culture method was employed, followed by the liquid culture method and soil burial technique. Notably, after two months in liquid medium, the PU film was totally degraded into smaller pieces. Based on a comprehensive literature search, it can be stated that this is the first report showing *A. tubingensis* capable of degrading PU. This work provides insight into the role of *A. tubingensis* towards solving the dilemma of PU wastes through biodegradation.

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Biography:

Dr. Sehroon Khan is a postdoctoral researcher at the Kunming Institute of Botany, Chinese Academy of Science, which he joined in November 2014. He was previously an assistant professor at the Institute of Biotechnology and Genetics Engineering, The University of Agriculture, Peshawar, Pakistan. Dr. Khan works primarily on sustainable agriculture, environmental protection, biopesticides engineering, plant protection and plastics biodegradation. His research focuses on the isolation and identification of entomopathogenic, phytopathogenic or plastic-degrading fungi and their utilization against insect pests, plant pathogens and plastic waste. Dr. Khan is currently investigating the activation of plant basal immunity through the isolation of elicitor proteins from phytopathogenic fungi/oomycetes as an environmentally sustainable strategy for pest and disease prevention. He is expert in the isolation, identification and culturing of mycoparasitic/hyperparasitic fungi from diseased plants in preparation for their use as biocontrol of phytopathogenic fungi. Dr. Khan's recent and current projects include research on cloning the elicitor/insect toxin protein gene in endophytic bacteria (for heterologous secretion expression), and characterization of the engineered bacterial strain on biological control; and investigation of plastics biodegradation using crickets, mealworm, fungi and bacteria.

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Towards Extracellular Secretion of Recombinant Proteins Using Antisense Technology

Shahin Heshmatifar, Department of Biochemical Engineering , UCL. UK

Abstract:

Antisense RNA can target and inhibit the synthesis of proteins made by the cell, particularly outer membrane proteins to facilitate secretion of the recombinant product out of the cell during fermentation. This project aims to investigate the impact of inhibition of synthesis of selected outer membrane proteins on the secretion levels, thus having an effective release system. Various products such as alpha-amylase, Fab fragments have been investigated. In case of high secretion yields, the methodology can be adapted by the industry to eliminate cell lysis steps and the overall number of recovery and purification steps in the manufacturing of recombinant proteins can be reduced. The success of this project will be significantly attractive for the industry and it can lead to a new bioprocess strategy within the industry. Yields of 60% has been achieved, an increase from 10%. Yield defined as % of total product in the supernatant. Potential significance for the industry include elimination of cell disruption steps in a bioprocess, significant reduction in levels of contaminants such as HCP, DNA, proteolytic activity is greatly reduced in the culture medium, reduction in number of unit operations in a bioprocess and reduction in process running cost and time.

Biography

Shahin Heshmatifar, Experienced Teaching Fellow with a demonstrated history of working in the research industry. Skilled in Medical Microbiology, Fermentation Process Development, SDS-PAGE, Molecular Biology, and Biotechnology. Strong education professional with a Doctor of Philosophy (Ph.D.) focused in Biochemical Engineering from University College London, U. of London.

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IDENTIFICATION OF NOVAL PEPTIDES FROM THE HEART TISSUE OF GOAT AND CHICKEN AGAINST HUMAN PATHOGENIC BACTERIA.

Dr. T.S.Saravanan,
Professor of Biotechnology, Dr.MGR Edu. & Res. Institute, (Deemed to be University), INDIA.

The cathelicidin family of antimicrobial peptides have been identified in several mammalian species like rabbit (rCAP-18), mouse and rat (CRAMP), guinea pig (CAP-11, BMAP-27, 28 and 34), sheep (SMAP-29 and -34), goat (MAP-28 and -34), pig (pMAP-23, -36 and -37) and primates (human LL-37 and rhesus 37) (Zelezetsky et al., 2006). Cathelicidin genes homologous to the human CAMP gene coding for LL-37 have been sequenced and analysed in 20 primate species, including Great Apes, hylobatidae, cercopithecidae, callithricidae and cebidae (Zelezetsky et al., 2006). The airway epithelial cells of human produce □-defensins and cathelicidins (LL-37) (Hiemstra, 2007). Chromek et al., (2006) described the production and function of the human cathelicidin antimicrobial peptide LL-37, its precursor hCAP-18 and its ortholog CRAMP in epithelial cells of human and mouse respectively. Sang et al., (2007) have reported the cloning, tissue expression and biological activity of a novel canine cathelicidin (K9CATH). The anti HIV activity of some AMPs and their derivatives have also been detected (Bergman et al., 2007; Wang et al., 2008). Okuyama-Nishida et al., (2009) have also investigated the death prevention in bacterium-infected mice by a synthetic antimicrobial peptide, L5 through activation of host immunity. A recombinant CM4 antimicrobial peptide was expressed in E. coli using pET32a vector and purified by reverse phase HPLC (Zhou et al., 2009). However a very few works have been done in this area. For example, the interaction of indolicidin, a 13 residue peptide rich in tryptophan and proline and its analogues with model membranes was studied by Subbalakshmi et al., (1998). Ambika et al., (2008) have cloned and characterized a goat cathelicidin cDNA. Chellapandi and Jebakumar (2008) have also substanciated the antibacterial activity of 10 - 17 kD ranged proteins of snake venoms. Recently for the fisrt time, We, Sundaramoorthy and Saravanan (2010) have substantiated the antibacterial properties of goat and chicken heart tissue proteins. Subsequently we purified a 16 and 13 kDa non-hemolytic antibacterial peptide against S. typhi and P. aeruginosa from goat and chicken heart tissues respectively (Sundaramoorthy and Saravanan, 2011a & b). Recently we have also identified a 215 bp cDNA from the heart tissues of chicken by RT-PCR and the sequential study has revealed that the deduced peptide was a 5.5 kDa cathelicidin like peptide with 59 amino acids (Sundaramoorthy et al. 2014).

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Novel Regenerative Disease-Modifying Therapies for Alzheimer's Disease

Leen Kawas, M3 Biotechnology, Inc. Seattle, WA, USA

Abstract

Alzheimer's disease (AD) is the greatest medical challenge of the 21st century. Current treatment options remain palliative and do not treat the underlying cause of neurodegeneration in AD. Without an effective disease-modifying treatment, the current AD and dementia population is projected to reach over 130 million worldwide by year 2050; posing an urgent public health challenge today.

M3 Biotechnology, Inc. (M3) is a clinical-stage biotechnology company with a platform of novel small molecule therapeutics for neurodegeneration with a focus on AD. M3's lead therapeutic is a modulator of a novel neurotrophic growth factor shown to slow disease progression, exhibit neuroprotective properties and restore cognitive function in preclinical studies of AD. In addition, the lead compound induced EEG changes in wild-type and APP/PS1 transgenic mouse model of AD, suggestive of a potential translatable biomarker to indicate CNS penetration and effective therapeutic change in human subjects. M3's lead therapy is being assessed in human clinical trials to study drug safety, tolerability, pharmacokinetics and EEG as a pharmacodynamic biomarker.

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Principles and guidelines for good manufacturing practices (GMP) in Investigational Medical Products and the application in Advance Therapy Investigational Medical Products for the safety of patients

MARIA TERESA VAZQUEZ CALO[1], CRISTINA VAZQUEZ CALO[1],

1. Dutilh Abogados Partner Life Sciences & Healthcare, Spain

The manufacturing of investigational medicinal products presents additional challenges comparing to the manufacturing of authorised medicinal products because there are no fixed routines, there is a variety of clinical trial designs and consequently packaging designs that the new Regulation (EU) 2017/1569 of 23 May 2017 addresses supplementing the Regulation (EU) No 536/2014.

Regarding advanced therapy investigational medicinal products, their special characteristics require the adaption of the provisions on good manufacturing practice in accordance with a risk-based approach. It is important to recognise some flexibility in the application of the GMP requirements so that the Advance therapy investigational medical products manufacturer can implement the measures that are most appropriate having regard to specific characteristics of the manufacturing process and of the product.

Any flexibility applied must, however, be compatible with the need to ensure the quality, safety and efficacy of the product. According to new Regulation (EU) 2017/1569, the good manufacturing principles shall be adapted to the specific characteristics of the Advanced Therapy Medicinal Products (ATMP) when used as investigational medicinal products. Investigational medicinal products, which are at the same time advanced therapy medicinal products, shall be manufactured in accordance with specific guidelines that EMA is now discussing.

The future GMP for ATMP, which consulting period was closed last April, have some deficiencies that Pharmaceutical Inspection Convention (PIC) has shown sending a letter to EMA. Should these deficiencies affect to Advanced Therapy Investigational Medicinal Products too?

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How to run Clinical Trials for Bio pharmaceutical products, get approval market by planning efficiently.

Marco Antonio Cid Lopez, Investigación Biomedica para el Desarrollo de Fármacos SA de CV

Abstract

It is becoming increasingly important to know the simplest and least costly way to develop Biopharmaceutical products in the world. The objective is to present to the assistant how to look for robust clinical data to seek approval in the target markets. We will review the best strategies in multicentre studies, the phases of their development and how a competitive advantage is developed from the scientific evidence.

Biography

Marco Antonio Cid López. I have worked for more than 15 years in the research and development of medicines. I am a Biomedical Chemist by La Salle University (Mexico), I studied at York College of Clinical Research (Canada), participating as an intern at Toronto General Hospital, conducting concept tests of potential drugs and Phases 1. I have worked in the Research and Development department for 10 years in companies such as ROCHE and Merck Sharp & Dohme. Develop the Department of Clinical Research of Sophia Laboratories (ophthalmic) where it leads to pipeline 16 potential products.

5 years ago We developed “Investigacion Biomedica”, in which we implement Phase 1 to Phase 4 research protocols. I am a consultant for clinical research projects in Latin America, based on the US IND of the FDA and the ICH

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