

Pradip Paul

**"Scope for Tools in Risk Management
with Adverse Drugs Reactions "**



The role of Biomedical Engineering in drug development of new chemical entities (NCE) is well known. Once an NCE is applied to humans as an experimental drug and is subsequently marketed

after FDA approval, the safety of the drug is strictly monitored under guidelines set by the regulators like FDA in the USA, EMEA in Europe, Ministry of Health in Canada, etc. The pharmaceutical and biotechnology companies are required to conduct such monitoring.

Adverse drug reactions (ADR) are often reported to the pharmaceutical companies where the Drug Safety Department (DSD) handles them. By developing a Risk Management plan for each NCE in the market. For a global company, the task is multifaceted with the requirement to harmonize worldwide.

An overview of the ADR handling in a Drug Safety department was presented. Cases were described where Biomedical Engineers contributed to the paradigm of Drug Safety.

Dr. Paul received his M.S. degree in Biomedical Engineering from NJIT in 1988, after having received his Medical degree from Dhaka Medical College in 1973 and engaging in clinical practice between 1976 and 1985. Between 1987 and 1995 he managed various clinical trials for Ciba-Geigy. From 1996-1999 he worked in clinical surveillance for Charles Pfizer, and since 1999 has been the Director of Global Medical Safety & Surveillance of Berlex Pharmaceuticals.

Biomedical Engineering

at

NJIT

**The New Jersey Institute of
Technology**

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**Bachelors Degree
Masters Degree
Doctoral Degree
in Biomedical Engineering**

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McNair Scholars

Among the three undergraduate Biomedical Engineering students who were recognized for their research on April 23

Tamalois Banks

Adviser: Prof. Richard Foulds

"Measures of Bimanual Coordination for Persons with Hemiplegia"



The simultaneous use of both limbs at the same time is very important in order to carry out certain tasks. The present research is looking into how an unaffected limb can aid the affected limb during coordination by using

bimanual control of neural movements. By placing sensors on the limb that are attached to a "Flock of Birds", the position of the limb is measured. A MATLAB program then analyzes the position and velocity of the limb movements. This advancement can be useful in therapy for individuals who have suffered from stroke.

Celena Daniels

Adviser: Prof. Treena Arinzeh

"The Study of a Bone-like Extracellular Matrix Produced by Human Mesenchymal Stem Cells on a Ceramic Scaffold"



Bone defects in humans can be caused by a number of different conditions ranging from cancer to trauma.

Although there are synthetic implants or grafts that can replace the defective parts of the bone, there are materials

have severe limitations. This research entails investigating, in vitro, 20/80 and 60/40 hydroxyapatite/tricalcium phosphate ceramics as scaffolds for HMSCs to promote bone regeneration. Each ceramic is seeded with HMSCs and are fed with osteogenic culture medium to promote differentiation into bone cells.