# MEDICAL DEVICES: FROM IDEA TO FDA APPROVAL

Process and Tips

DATE: Saturday 29th April 2017

PLACE: Saint-Joseph University of Beirut

Campus des Sciences Médicales – Amphi C

TIME: 14:30-18:30

Under the sponsorship of Johnson & Johnson and University St. Joseph.

In collaboration with Banque Du Liban, AUB, LHMA &Health Care Technology Management and Advancement

This conference will provide insights on Medical Devices development from idea to FDA approval.













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#### **OVERVIEW**

During the conference organized by HTMA on March 4, it became obvious that innovation in healthcare technologies in USA and Europe is mostly done by companies of less than 10 employees. As such there is a great opportunity for innovation in our country.

#### **OBJECTIVES**

1.

To provide practical steps for innovators to follow while developing their products.

2.

Understand how to approach international companies like Johnson & Johnson with ideas.

#### **GENERAL INFORMATION**

#### WIFI

For Wi-Fi Access

Username: HTMA- guest2017

Password: usj2017

#### **CONTACT INFORMATION**

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### **ORGANIZING COMMITTEE**

#### Mr. Bassam Tabshouri

Director, Medical Engineering,

American University of Beirut (AUB)

Chair, Healthcare Technology Management and Advancement (HTMA\*), Lebanon

#### Mr. Said Haddad

**Managing Director** 

Johnson & Johnson Medical Devices Middle East

#### **Dr. Saad Andary**

Vice Governor, Lebanese Central Bank

#### Dr. Dolla Karam Sarkis

Vice President for research, St. Joseph University

### **INVITED SPEAKERS**

#### Mr. Chris Papa

Director Energy R&D, Energy

Johnson & Johnson USA

#### Mr. Mark Hanes

Worldwide HIP Development Director & WW Research Director, Hip Development

Johnson & Johnson USA

## **PROGRAM**

15:00	Welcome messages
15:30	Product Development by Mark Hanes (Johnson & Johnson)
	- Introduction
	- Creation of a New Product
	· Unmet need
	- Requires more than just a "good idea"
	· Who is involved?
	· Development Process
	- Concept
	- Specification
	- Design
	- Verify and Validate
	- Build
	- Follow-up
	· Things to consider
	· Conclusions
16:30	Q&A
16:45	Coffee break
17:00	Product Development by Chris Papa (Johnson & Johnson)
	- Approaching J&J with an idea
	· JNJ Idea Portal awareness
	· Apply for patent protection before approaching any company with an
	idea
	· JNJ sorting hierarchy
	· Internal JNJ idea review
	· Uncovering an Opportunity
	- Highlights of the development process for a device with embedded software $% \left( 1\right) =\left( 1\right) \left( 1\right$
	· Design Process – DMADVV
	· Development of a product with embedded software
	- Safety Considerations
	- Regulatory Considerations
	- Design Documentation
18:00	Q&A
18:15	Closing notes
18:30	Networking

# **NOTES**

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