TABLET MANUFACTURING
Process Training

MARCH 6 - 9

Long Island University, Brooklyn, NY



LECTURES & LABORATORY EXERCISES WILL COVER

Formulation Development • Modified Release Technologies
Tablet Tooling Design • Tablet Scale Up Issues

with HANDS-ON LEARNING where YOU OPERATE the equipment!

With the completion of the course, participants will earn 21.5 ACPE Pharmacists Accreditation hours.

EVENT HIGHLIGHTS

Granulation

- An overview of granulation principles and hot melt extrusion, including best practices will be presented using case studies, equipment and discussion.

Powder Characterization

- How to measure powder performance properties including density, flow, and cohesion.

Coating

- A host of factors can influence successful tablet coating. Learn the ins and outs of this process from industry leaders.

Compression

- How to utilize data from an instrumented rotary tablet press. Participants will receive a hands-on training opportunity.

Analytical

- It all starts with powder. Our experts will explain the importance of characterization, measurement, blending, and more.

REGISTER NOW!

NATOLI INSTITUTE FOR INDUSTRIAL PHARMACY RESEARCH & DEVELOPMENT at Long Island University | LIU Pharmacy

COURSE OVERVIEW

WELCOME!

When we founded the Natoli Institute for Industrial Pharmacy Research and Development, it was my intention that the laboratory would serve not only as a resource for research and troubleshooting, but also to provide opportunities for educational advancement in the industry. In less than a year, we have met, and surpassed, these aspirations. The Institute continues to complete meaningful research studies on tablet manufacturing at the university.

We have invited a group of the most knowledgeable industry veterans to present The Tablet Manufacturing Process. This course offers a comprehensive, hands-on experience with the tablet manufacturing process from formulation development to tablet design to tablet compression – all presented in our state-of-the-art lab on the Brooklyn campus of Long Island University.

Please join us to learn how to overcome a wide array of tableting challenges as well as the science behind industry best practices. We are very excited to announce that participants will earn 21.5 hours of ACPE Pharmacists Accreditation through completion of the course.

We look forward to welcoming you to our facility and encourage you to register early as we anticipate the course filling quickly!

DALE NATOLI
President
Natoli Engineering Company
636.926.8900 • natoli.com

natoli.com

WHO SHOULD ATTEND

This course is designed for **contract pharmacists, formulators, managers, tablet press technicians** and those who want to better understand the tablet manufacturing processes.

LEARNING OBJECTIVES

Participants of Tablet Manufacturing Process Training will finish with an understanding of fundamental concepts including:

- Fluid Bed Operations
- Dry Granulation
- Wet Granulation
- Hot Melt Extrusion
- Tablet Coating
- Tablet Press Operations

ABOUT NATOLI INSTITUTE

The Natoli Institute can structure use of the facility to accomplish simple one of a kind experiments or assist a client to build a program for ongoing formulation compression and testing. Some equipment found at the Natoli Institute includes:

- Roller Compactor
- Fluid Bed System
- 8 and 16 Station Rotary Tablet Press
- Single Station Tablet Press
- High Shear Wet Granulator
- Hot Melt Extruder
- Vector GMX-Lab Micro
- Lab Dev Coating System
- Vector VFC-LAB 1 Flo Coater

The Natoli Institute is open and actively managing projects for customers in need of data and knowledge that can only be obtained by utilizing a facility like the Natoli Institute. Some typical projects addressed include:

- Tablet sticking and picking screening
- Formulation development
- Tablet scale up troubleshooting
- Coating studies
- Bioavailability and dissolution studies

HOTEL INFORMATION

Scan to reserve a room

Sheraton Brooklyn New York Hotel

228 Duffield Street, Brooklyn, NY 11201

To make reservations, guests can call the reservations department at +1 718.855.1900 and request the negotiated rate for LIU-Natoli. You may also make reservations online using: https://goo.gl/vSL4Cb. Please book your room early as rooms available at this rate are limited. *See map on back page for the location of the hotel.*

AGENDA-AT-A-GLANCE

DAY ONE I SUNDAY, MARCH 6, 2016

5:00 pm	**Registration/Course Kickoff**
5:30 pm	**Welcome Dinner** *Sheraton Brooklyn New York Hotel, 228 Duffield Street, Brooklyn, NY 11201*
6:30 pm	**Course Overview & Speaker Introduction**

DAY TWO I MONDAY, MARCH 7, 2016

8:00 am	**Tablet Press Fundamentals** *Robert Sedlock*
9:00 am	**Direct Compression Blend Preparation and Considerations** *Joe Zeleznik*
10:00 am	Break

10:20 am	**Roller Compaction Granulation Technology** *Nicholas Slater*
11:20 am	**Fluid Bed Granulations and Wurster Coating** *Ed Godek*
12:20 pm	Lunch & Group Photo

LABORATORIES

	GROUP 1	GROUP 2	GROUP 3	GROUP 4	GROUP 5	GROUP 6
1:30 pm **Lab Session 2A**	Dry Granulation	Wet Granulation	Fluid Bed Operations	Hot Melt	Tablet Press Operations	Tablet Coating
3:00 pm **Lab Session 2B**	Wet Granulation	Fluid Bed Operations	Hot Melt	Tablet Press Operations	Tablet Coating	Dry Granulation
4:30 pm	Break					
4:45 pm **Lab Session 2C**	Fluid Bed Operations	Hot Melt	Tablet Press Operations	Tablet Coating	Dry Granulation	Wet Granulation

DAY THREE I TUESDAY, MARCH 8, 2016

8:00 am	**Excipient Selection** *Tony Carpanzano*
9:00 am	**Incorporating QbD Principles with the Product Development Process** *Dr. Kenneth Morris*

10:00 am	Break
10:20 am	**Modified Release Overview** *Piyush Patel*
11:20 am	**Wet Granulation** *Nicholas Slater*
12:20 pm	Lunch

LABORATORIES

	GROUP 1	GROUP 2	GROUP 3	GROUP 4	GROUP 5	GROUP 6
1:30 pm **Lab Session 2A**	Hot Melt	Tablet Press Operations	Tablet Coating	Dry Granulation	Wet Granulation	Fluid Bed Operations
3:00 pm **Lab Session 2B**	Tablet Press Operations	Tablet Coating	Dry Granulation	Wet Granulation	Fluid Bed Operations	Hot Melt
4:30 pm	Break					
4:45 pm **Lab Session 2C**	Tablet Coating	Dry Granulation	Wet Granulation	Fluid Bed Operations	Hot Melt	Tablet Press Operations

DAY FOUR I WEDNESDAY, MARCH 9, 2016

8:00 am	**Characterizing Powder Behavior in Relation to Tablet Manufacture** *John Yin*
9:00 am	**Compression Tools, Standards, Practical Troubleshooting and Tablet Design** *Bill Turner*
10:00 am	Break

10:20 am	**Solubilization 101: Finding Solutions for Poorly Soluble Drugs** *Dr. Shaukat Ali*
11:20 am	**Hot Melt Extrusion** *Dr. Rutesh Dave*
12:20 pm	Lunch & Wrap Up

COURSE SPEAKERS

DR. RUTESH DAVE is currently Associate Professor and Division Director of Pharmaceutical Sciences at the Arnold and Marie Schwartz College of Pharmacy and Health Sciences at LIU. He teaches Pharm.D. and graduate pharmaceutics related courses and maintains an active research laboratory. Prior to joining academia, he worked in the pharmaceutical industry as a senior scientist and as a group leader developing small molecules and new technologies.

CHAIRPERSON

Dr. Dave's lab is divided into four major areas of research: new technology for delivery of insoluble drugs, generic development, fundamental formulation studies and powder characterization. Dr. Dave has published papers extensively in peer-reviewed journals and has presented at several global conferences. He is also on the editorial board and a reviewer of several peer reviewed journals. Dr. Dave is a recipient of the Founders Award for his exceptional service and the Newton Award for excellence in teaching at LIU.

DR. SHAUKAT ALI has over 21 years of experience in the pharmaceutical industry including 11 years at BASF, where he supports solubilization, instant and modified release platforms, and APIs. His areas of expertise include solid dispersions, liposome drug delivery, controlled release, transdermal, and film development technologies.

Dr. Ali is a member of the editorial advisory boards of American Pharmaceutical Review, Biopharma Asia, Contract Pharma, Drug Delivery & Development, International Journal of Pharmaceutical Investigation, Journal of Pharmaceutical Sciences and Pharmacology, and Journal of Analytical & Pharmaceutical Research. He is also a member of USP panel of experts for General Chapters-Physical Analysis. He received his Ph.D. in Chemistry and pursued his postdoctoral training at the University of Minnesota and Cornell University. He has authored over 37 scientific articles and is the inventor of 14 U.S. patents.

ED GODEK is Glatt Air Techniques' Equipment and Engineering Division's prime technical resource for process technology. Ed conducts process training and troubleshooting for Glatt customers, speaks at industry seminars, and has written articles for publications such as Tablets and Capsules, Pharmaceutical Manufacturing, and Pharmaceutical Technology. He is also involved with the development and assessment of new process equipment.

Mr. Godek has over 12 years of experience working directly in the area of fluid bed processing, and over 23 years of experience in the pharmaceutical industry. His expertise in process operations includes granulation, blending, compression, Wurster and tablet coating for the development of oral solid dose products. He has also overseen process scale-up, tech transfer, and process validation for both internal and client projects. He has held scientific and management positions in R&D and Manufacturing with ESI Lederle, Purdue Pharma, Pfizer, and Barr Laboratories. Ed holds a Bachelor's Degree in Chemical Engineering and a Master's Degree in Chemical Engineering.

PIYUSH PATEL has more than 10 years of experience in modified release solid oral dosage form & immediate release liquid dosage form. He is responsible for providing technical support and generating application data for formulation excipient and polymers offered by Colorcon. His prior experience includes work as a Product Development Scientist at Colorcon generating application data on matrix formulation and push pull osmotic technologies. He has worked for Medico labs as a R&D scientist developing OTC oral liquid dosage form.

He earned his MPharm in Pharmaceutical Sciences in Nanotechnology Drug Delivery Research from Curtin University of Technology, Australia. He has contributed posters and peer-reviewed articles in the areas of Nanotechnology, Hydrophilic Matrix formulation and Push Pull Osmotic Technology.

BILL TURNER is the Technical Service Manager of Tooling and Tablets at Natoli Engineering Company, Inc. Prior to that position he was the Engineering Manager and Tablet and Tool Designer for 20 years as well as a Technical Customer Service Representative for over 15 years.

He educates and trains Natoli sales and service staff and conducts training seminars for the industry in tablet design, tool design, and troubleshooting, both in-house, and on site.

JOHN YIN is educated in Engineering Chemistry at the State University of New York at Stony Brook. John has considerable international experience in applications as well as sales and marketing instruments for surface chemistry and particle characterization.

Powder characterization company Freeman Technology appointed Mr. Yin as Application Specialist for the U.S. in 2007. This is the company's first direct appointment in the US market.

ROBERT SEDLOCK is the Director of Technical Training and Development for Natoli Engineering Company. He has been serving the tablet compression industry for over 18 years. His early experience spans strain gauge force measurement technology and data acquisitions systems.

Mr. Sedlock has many published technical articles in publications such as Pharmaceutical Technology, and American Association of Pharmaceutical Scientists. He is a past technical advisory board member for Tablets and Capsules. He also presents at many hands on training seminars hosted by universities worldwide.

Mr. Sedlock's areas of expertise include instrumentation systems, troubleshooting compression and scale up issues, optimizing formulations and comprehensive tablet press training. His current responsibilities include global solid dosage customer support, training seminars, contract compression services and continuous research at the Natoli Institute of Industrial Pharmacy located at the Long Island University AMS College of Pharmacy and Health Sciences in Brooklyn, New York.

TONY CARPANZANO worked in pharmaceutical product development for 32 years. His experience includes liquids formulation, pre-formulation, exploratory development, technical services and clinical manufacturing, with a major focus on advanced solid dosage form and modified release dosage form development. He holds patents on modified release technologies and abuse-resistant/abuse-deterrent technologies.

He has worked for companies including Richardson-Vicks, Procter & Gamble, generic manufacturers, Schein and Copley Pharmaceutical, Purdue Pharma and Penwest, and has spent the last four years working in the excipients industry for JRS Pharma, LP, as Director of R&D. He is also a licensed Pharmacist.

DR. KENNETH MORRIS holds a dual B.S. in Chemistry and Aquatic Biology, and an M.S. in Pharmaceutical Chemistry. He received his Ph.D. from the University of Arizona and joined E.R. Squibb and Sons where he developed the Physical Characterization group and co-developed the Materials Science function. He went on to form the Preformulation/Physical Pharmacy group in the Bristol-Myers Products organization, while concurrently serving as an adjunct professor at Rutgers College of Pharmacy and St. John's University. In 1997, he moved to the Industrial and Physical Pharmacy department at Purdue, continuing work in Pharmaceutical Materials Science and Industrial Pharmacy as a professor and associate head. In 2008, Dr. Morris helped establish the new College of Pharmacy and Ph.D. program in Pharmaceutical Sciences at the University of Hawaii at Hilo where he was Department Chair and Graduate Council Chair.

Dr. Morris currently serves as Professor and founding Director of the Lachman Institute for Pharmaceutical Analysis at LIU. His research and teaching interests include: analytical tools for solid state characterization, the study of the impact of processing on the physical characteristics of formulation components and on subsequent dosage form performance, pharmaceutical unit operation optimization, advanced applications of powder x-ray diffraction and dielectric analysis, the study of the association of water with pharmaceutical solids, and modeling and methods for monitoring processing unit operations. Dr. Morris is an AAPS fellow and was the Purdue University Site leader for the NSF Engineering Research Center for Structured Organic Composites. He is a special government employee and past-chair of the U.S. FDA Scientific Advisory Committee for the Office of Pharmaceutical Sciences.

NICHOLAS SLATER is a senior process development scientist with primary responsibilities at Freund-Vector includes working closely with customers on process development, scale-up, and process troubleshooting. He has worked extensively with pharmaceutical, nutraceutical, agricultural, pyrotechnics, and food industries. Mr. Slater has also presented and conducted hands-on laboratory training at multiple seminars throughout the world. These seminars have covered roller compaction, fluid bed granulation, fluid bed coating, and pan coating technology. He received his Bachelor of Science from Iowa State University and currently sits on the Board of Directors for the Institute of Briquetting and Agglomeration.

JOE ZELEZNIK serves as Manager of Technical & Regulatory Affairs with MEGGLE USA, Inc. He is responsible for providing formulation and product application guidance. Prior to joining MEGGLE USA, he was Associate Director, R&D with JRS PHARMA and Research Manager with Penwest Pharmaceuticals Co. Mr. Zeleznik has over 20 years experience in the pharmaceutical industry, with specialization in the development and application of high functionality excipients, in particular, co-processing applications for the enhancement of excipient and pharmacologically active ingredient performance. He holds several patents in areas of product and process development, formulation development, and API co-processing. Mr. Zeleznik has authored or co-authored several articles published in various industry journals and holds a Master's Degree in Chemistry from the State University of New York.

DAY ONE I SUNDAY, MARCH 6, 2016

5:00 pm **Registration/Course Kickoff**

5:30 pm **Welcome Dinner** *Sheraton Brooklyn New York Hotel, 228 Duffield Street, Brooklyn, NY 11201*

6:30 pm **Course Overview & Speaker Introduction**

DAY TWO I MONDAY, MARCH 7, 2016

LECTURES & LABORATORIES

8:00 am **Tablet Press Fundamentals**
Robert Sedlock
Natoli Engineering Company
Director of Technical Training & Development
An overview of the available industry tablet presses. A focus on the rotary tablet press process from the die filling process, compression events, ejection and take off stage. Common industry compression/scalability issues will be discussed and ways to remediate them with an instrumented tablet press. Compaction profile and strain rate data will be provided to show the comparison of a robust and problematic formulation.

9:00 am **Direct Compression Blend Preparation and Considerations**
Joe Zeleznik
Meggle USA
Manager of Technical and Regulatory Affairs
Direct compression is a cost effective alternative to complex processes such as granulation; however, cost is only one consideration when selecting direct compression blending as a unit process. Direct compression blend preparation involves a number of considerations to ensure blend uniformity. Equipment and ingredient selection as well as blending strategy are a few of the factors involved toward developing a robust process and quality formulation. Other factors may also influence successful direct compression formulations. The speaker will examine various aspects related to direct compression blending as well as discuss direct compression advantages and disadvantages.

10:00 am Break

10:20 am **Roller Compaction Granulation**
Nicholas Slater
Freund-Vector Corporation
Senior Process Development Scientist
An overview of Roller Compaction Technology that will cover equipment design, formulation issues and troubleshooting common granulation problems.

11:20 am **Fluid Bed Granulation and Wurster Coating**
Ed Godek
Glatt Company
Manager of Process Technology
Part 1: An overview of the basic concepts of fluid bed granulation processing. The focus will be on basic machine design and the development of critical process parameters to achieve a granulation suitable for compression.
Part 2: An overview of the basic concepts of Wurster coating technology. The focus will be on machine design and the development of critical process parameters to achieve controlled release multiparticulates suitable for encapsulation or compression.

12:20 pm Lunch & Group Photo

LABORATORIES

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1:30 pm **Lab Session 2A**	Dry Granulation	Wet Granulation	Fluid Bed Operations	Hot Melt	Tablet Press Operations	Tablet Coating
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4:30 pm	Break					
4:45 pm **Lab Session 2C**	Fluid Bed Operations	Hot Melt	Tablet Press Operations	Tablet Coating	Dry Granulation	Wet Granulation

LECTURES & LABORATORIES

8:00 am **Excipient Selection**
Tony Carpanzano
JRS Pharma
Director of R&D
This presentation outlines key considerations for selecting excipients for a formulation. Common excipients used for solid oral dosage forms will be discussed. The function and properties of each excipient will be covered as well as advantages and disadvantages of each excipient.

9:00 am **Incorporating QbD Principles with the Product Development Process**
Dr. Kenneth Morris
Long Island University
Director, Lachman Institute for Pharmaceutical Analysis
The Quality by Design (QbD) FDA initiative was launched in response to demands from the changing state of pharmaceutical products and the industry. The principles remain the same, good science for sound product and process design. What has evolved is the agencies approach to encouraging QbD and the technologies to help with implementation at pharmaceutical companies. This offering will review the QbD paradigm and provide a framework to aid in incorporating the principles into a rationale product development process.

10:00 am Break

10:20 am **Modified Release Overview**
Piyush Patel
Colorcon
Formulation Technologies Manager
An overview of modified release options are covered in this presentation. Specific release profile types will be covered such as first order release, zero order release, biphasic release and delayed release. Technologies include hydrophilic matrices, multiparticulates, osmotic pumps and enteric coated products.

11:20 am **Wet Granulation**
Nicholas Slater
Freund-Vector Corporation
Senior Process Development Scientist
An overview of wet granulation methods will be presented. Equipment design, process principles, and important process factors will be discussed. Case studies will be used to show the differentiation between the methods.

12:20 pm Lunch

LABORATORIES

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ACPE - Pharmacists Accreditation

Credit Hours: 21.5 Expiration Date: 10/07/2018 ACPE UPN: 0042-0000-15-023-L04-P
Release Date: 03/7/2016

The Arnold & Marie Schwartz College of Pharmacy and Health Sciences is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Credit will be issued upon attendance at complete activity and completion of post course evaluation at LIU RxSchool.

Target audience: Pharmacists interested in manufacturing.

This is a knowledge based activity.

We will not be giving partial credit. Credit will be given only to those completing the entire course after completion of the evaluation.

8:00 am **Characterizing Powder Behavior in Relation to the Tablet Manufacture**

John Yin
Freeman Technologies
Application Specialist

This presentation will cover the following topics:

- An overview of some powder processing challenges
- Why we need to measure powder characteristics and flow properties in particular
- A review of traditional measurement techniques with their strengths and weaknesses
- Advances in modern instrumentation and the benefits of the latest powder characterization techniques.
- The need to identify Critical Quality Attributes in relation to formulation and process optimization
- How we propose that you quantify and utilize your extensive powder processing experience
- Utilizing powder characterization techniques to improve and streamline the scale-up process
- Examples of how powder characterization techniques can be used as Process Analytical Technology (PAT).
- Employing the FT4 Universal Powder Rheometer in real powder processing applications including QbD, hopper flow, mixing& blending, filling, compression and many other processes

9:00 am **Compression Tools, Standards, Practical Troubleshooting and Tablet Design**

Bill Turner
Natoli Engineering Company
Technical Service Manager of Tooling and Tablets

This presentation will cover the following topics:

- Tool terminology
- Understanding TSM & EU specifications
- Common, and not so common, tool configurations
- Troubleshooting typical tool and tablet compression issues:
  - Critical tool dimensions and how they affect tablet quality and consistency
  - Sticking & picking
- Capping and laminating
- Head wear
- Spots and dark specks on tablets
- Tool binding
- Tablet twinning
- Tablet logo legibility

10:00 am Break

10:20 am **Solubilization 101: Finding Solutions for Poorly Soluble Drugs**

Dr. Shaukat Ali
BASF Corporation
Technical Support Manager

This presentation will focus on the characteristics and utilities of polymers in the development of solid dispersions by hot melt extrusion (HME). The screening and the processing conditions of APIs with polymers in HME will also be reviewed and discussed.

11:20 am **Hot Melt Extrusion**

Dr. Rutesh Dave
Long Island University
Director, Division of Pharmaceutical Sciences

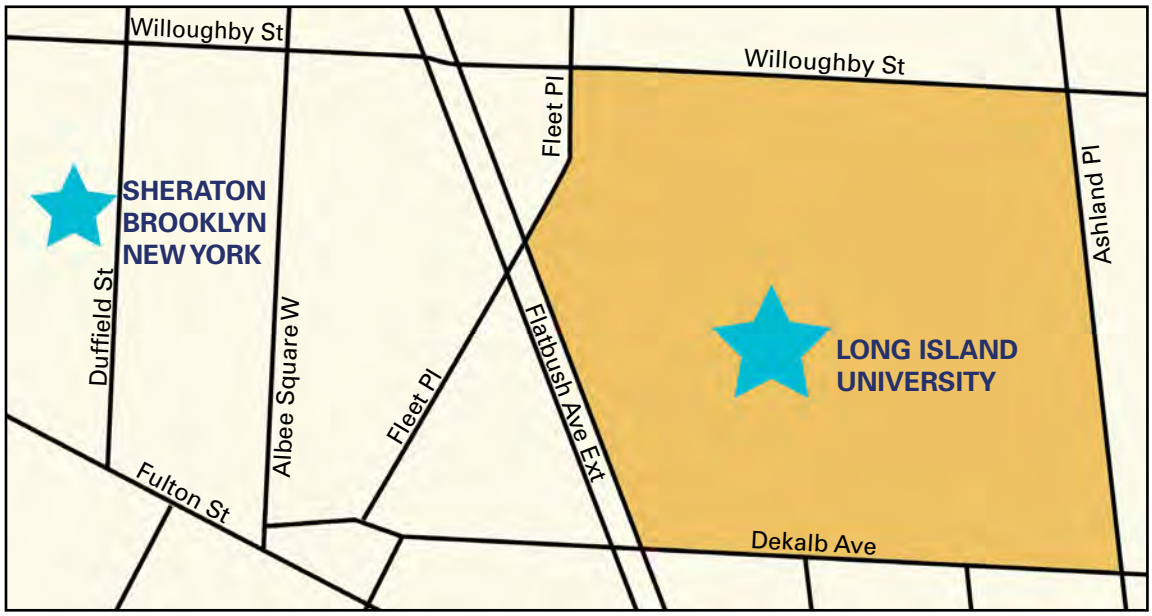
This course will cover the following objectives:

- What is solid dispersion and its role in current pharmaceutical related industries
- Enhancement of solubility using melt extruder
- Difference between single and twin screw extruder
- Tableting consideration after utilizing melt extruder
- Stability concerns
- Formulation development consideration while using melt extruder

12:20 pm Lunch & Wrap Up

Questions? Comments?

Do you have a question or comment that you would like to be addressed at this event? Please email Robert Sedlock at rsedlock@natoli.com



Entrance to Long Island University located at 75 Dekalb Ave

NATOLI INSTITUTE FOR INDUSTRIAL PHARMACY RESEARCH & DEVELOPMENT at Long Island University

THE NATOLI INSTITUTE
Arnold & Marie Schwartz
College of Pharmacy and Health Sciences
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CLICK HERE *to register online!*