In recent years, we have seen an increase in particle-related recalls and increased scrutiny of the visual inspection process during regulatory inspections. Since 2000, PDA has organized the Visual Inspection Forum to share current information on critical aspects of the visual inspection process to promote the operation of a robust and compliant inspection process. This Forum has grown into the leading event for those working in the field of visual inspection. Be sure to join us for the 2017 PDA Visual Inspection Forum, which will take place Oct. 23-24 in Bethesda, MD.

Take advantage of the opportunity to explore new developments in the field, including how to inspect and updates on the evolving regulatory expectations associated with the inspection process. Relevant chapters in the USP, including General Chapter <790> Visible Particulates in Injections and the new Information Chapter <1790> Visual Inspection of Injections, are included in this year’s program.

We will also have representatives from the FDA to discuss their views on particles in injectable products and inspection process expectations. An overview of PDA’s Technical Report providing guidance on those products that are difficult to inspect, such as lyophilized powders and strongly colored solutions, will be presented. Case studies will provide examples of how to deal with challenging inspections, the implementation of inspection methods and the analysis and trending of inspection results.

A further goal of this Forum is to build a network of experts and interested professionals working in this important and specialized field; therefore, we have built in question and answer sessions on important topics, including regulatory and compendial issues, particle control and characterization, case studies on inspection strategies and process implementation, special requirements for biopharmaceuticals, primary packaging materials, manual and automated inspection and more!

As in past years, this event will feature an exhibition where attendees can see the latest in commercial inspection hardware and discuss production needs with key suppliers of inspection systems and services.

Immediately following the Forum, Oct. 25-26, PDA Education is offering an optional two-day training course, An Introduction to Visual Inspection, at its Training and Research Institute facility. This course covers the basics of visual inspection, establishing and managing a visual inspection program and qualification and validation of inspection processes as applied to injectable products. This hands-on laboratory course allows for exploration of the practice of visual inspection along with its theory. The skills developed through this course may be applied to both manual human inspection and automated machine inspection.

We look forward to seeing you at this exciting and informative 2017 PDA Visual Inspection Forum!
GENERAL INFORMATION, REGISTRATION

FOUR WAYS TO REGISTER

1. Click pda.org/2017Visual
2. Fax +1 (301) 986-1093
3. Mail PDA Global Headquarters
   Bethesda Towers
   4350 East West Highway, Suite 600
   Bethesda, MD 20814 USA
   (301) 656-5900 ext. 115
4. Phone

VENUE
Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Rd.
North Bethesda, MD 20852
Phone: +1 (301) 822-9200
Website: www.bethesdanorthmarriott.com
Rate: Single: $239 plus applicable state and local taxes.
Cut-Off Date: Monday, September 25, 2017
(Availability may be limited. Requests will be processed on a first-come, first-served basis. Attendees staying within the PDA block will receive the Conference rate.)

CONTINUING EDUCATION CREDITS
PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the Continuing Pharmacy Education (CPE) Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

2017 PDA Visual Inspection Forum
ACPE # 0116-0000-17-011-L04-P | 1.2 CEUs
Type of Activity: Knowledge

LEARNING OBJECTIVES
At the completion of this event, attendees will be able to:

- Identify particulate inspection methods and equipment
- Identify critical parameters that affect the inspection process
- Develop state-of-the-art methodologies that reflect current industry knowledge
- Describe compendial requirements and regulatory trends to ensure their companies are meeting current and anticipated regulatory expectations
- Implement an effective and economical visual inspection process

WHO SHOULD ATTEND
Departments
Engineering | Manufacturing | Packaging | Process Development | Quality | Technical Services | Validation
Pharmaceutical/Biopharmaceutical Developers
Clinical Supplies | Parenteral Development | Process Development
Inspection Equipment Suppliers
Applications Development | Machine Design | Sales

CONFERENCE REGISTRATION HOURS
Monday, October 23: 7:15 a.m. – 5:15 p.m.
Tuesday, October 24: 7:30 a.m. – 5:30 p.m.

COURSE REGISTRATION HOURS
The Course will take place at the PDA Training and Research Institute at PDA’s Global Headquarters in Bethesda, MD.
Wednesday, October 25: 7:30 a.m. – 4:00 p.m.
Thursday, October 26: 7:30 a.m. – 4:00 p.m.

DRESS/ATTIRE
Business casual attire is recommended for all events. The temperature in the meeting rooms tends to be cool, so a jacket or sweater is advised for your comfort.

SPECIAL REQUIREMENTS
For information regarding special needs accommodations, please inquire at the Registration Desk. PDA is committed to make all events accessible to all individuals.

CONTACT INFORMATION
Forum Inquiries
Jason E. Brown
Assistant Director, Programs
Tel: (301) 656-5900 ext. 131
Email: brown@pda.org

Registration Customer Care
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Email: caballero@pda.org

Education Course Inquiries
Stephanie Ko
Senior Manager,
Lecture Education
Tel: +1 (301) 656-5900 ext. 151
Email: ko@pda.org
MONDAY, OCTOBER 23, 2017 AGENDA

7:15 a.m. – 5:15 p.m.
Registration Open

7:15 a.m. – 8:15 a.m.
Continental Breakfast

8:15 a.m. – 8:30 a.m.
Welcome and Opening Remarks
John G. Shabushnig, PhD, Principal Consultant, Insight Pharma Consulting, LLC, and Co-Chair, 2017 PDA Visual Inspection Forum Program Planning Committee

8:30 a.m. – 10:00 a.m.
P1: Regulatory Compendial Issues
Moderator: Markus Lankers, PhD, Director, Research & Development, rap.ID GmbH, and Co-Chair, 2017 PDA Visual Inspection Forum Program Planning Committee

Session Description: The first talk will provide regulatory perspectives on visual inspection issues. The second talk will summarize the recommendations on inspector training and qualification, supplemental testing and complaint investigation found in USP <1790>. It will also provide reference to other USP chapters that discuss particulate testing.

8:30 a.m. – 9:00 a.m.
Current Thinking on Visual Inspection/Particles and Experiences in the Field
Regulatory Representative Invited

9:00 a.m. – 9:30 a.m.
USP <790> and USP <1790>: Status and Recent Experience
John G. Shabushnig, PhD, Principal Consultant, Insight Pharma Consulting, LLC

9:30 a.m. – 10:00 a.m.
Questions & Answers/Discussion

9:45 a.m. – 6:45 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall
MONDAY, OCTOBER 23, 2017 AGENDA (CONTINUED)

10:45 a.m. – 12:15 p.m.
**P2: Particle Control and Characterization**
Moderator: Roy Cherris, Managing Partner, *Bridge Associates International*

*Session Description:* The first talk will address trials and tribulations of investigating, identifying and preventing sources of visible particulate matter. Evaluations of production and control processes for ampoules and lyophilized vials will be discussed. The second presentation will discuss both manual and automated analyses that can be applied to found particulate to identify unknown materials. Each method will include microscopy, FTIR, SEM-EDS, Raman and light obscuration particle counting and the results that can be expected. Pros and cons of manual versus automated methods will be discussed as well as what types of samples are best suited for each method. Case studies for various methodologies and examples of why a certain method was chosen for a particular type of sample will be presented. Additionally, the process of finding and submitting the most relevant reference materials for source determination and ultimately root-cause analysis will be discussed.

10:45 a.m. – 11:15 a.m.
**Particles: An Industry Perspective of “Practically/Essentially” Free**
Linda Wilding, Head of Quality Projects and Science Pharmaceuticals, *Takeda Austria GmbH*

11:15 a.m. – 11:45 a.m.
Cara Plese, Senior Scientist, *Gateway Analytical*

11:45 a.m. – 12:15 p.m.
Questions & Answers/Discussion

12:15 p.m. – 1:30 p.m.
**Exhibitor Roundtable Luncheon**
Connect with colleagues and exhibitors during lunch, while discussing “hot” topics in the industry.

1:30 p.m. – 3:00 p.m.
**P3: Challenging or Difficult-to-Inspect Products**
Moderator: John D. Ayres, MD, JD, Senior Medical Fellow, Product Safety Assessments, *Eli Lilly and Company*

*Session Description:* This session begins with a presentation that summarizes the topic of PM-DIP and the current PDA Task Force’s recommendations on these challenging products. The second presentation analyzes the results of a study of probability of detection (POD) shifts due to changes in a drug product’s appearance. In addition, it compares and analyzes POD shifts relative to clear, water-like solution due to changes in solution color, and separately, solution clarity, for several different types of typical defect materials found in parenteral manufacturing facilities.

1:30 p.m. – 2:00 p.m.
**Introducing the New PDA Technical Report on Particulate Matter in Difficult-to-Inspect Parenteral Products**
Roy Cherris, Managing Partner, *Bridge Associates International*

2:00 p.m. – 2:30 p.m.
**A Case-Study Examination of POD Shifts Generated by Difficult-to-Inspect Products**

2:30 p.m. – 3:00 p.m.
Questions & Answers/Discussion

3:00 p.m. – 3:45 p.m.
**Refreshment Break and Poster Presentations in Exhibit Hall**
3:45 p.m. – 5:15 p.m.
P4: Lyophilized Product Inspection
Moderator: Richard (Rick) Watson, Director, Sterile & Validation COE, Merck & Company/Merck Sharp & Dohme

**Session Description:** The first presentation will provide a summary of challenges related to visual appearance testing of freeze-dried products, particularly on how to judge the criticality of cake appearance. Furthermore, a harmonized nomenclature and description for variations in cake appearance from the ideal expectation of "uniform and elegant" will be provided. Finally, a science- and risk-based approach for establishing acceptance criteria for cake appearance will be discussed. The second presentation explores the collaborative work of two companies for the development and implementation of advanced software algorithms used on an automatic syringe inspection machine. Successful reduction of false fails while maintaining selective detection of foreign artifacts in viscous and other types of fluids will be addressed.

3:45 p.m. – 4:15 p.m.
Lyophilized Drug Product Cake Appearance: What is Acceptable?
Sajal Patel, PhD, Senior Scientist, MedImmune

4:15 p.m. – 4:45 p.m.
Advanced Particle Detection Software Algorithms to Reduce False Rejection in Viscous and other Types of Fluids
Al Goodwin, Principal Engineer, Machine Vision SME, Amgen, Inc.

4:45 p.m. – 5:15 p.m.
Questions & Answers/Discussion

5:15 p.m. – 6:45 p.m.
Networking Reception in Exhibit Hall

TUESDAY, OCTOBER 24, 2017

7:30 a.m. – 5:30 p.m.
Registration Open

7:30 a.m. – 8:30 a.m.
Continental Breakfast

8:30 a.m. – 10:00 a.m.
P5: Manual Inspection
Moderator: John G. Shabushnig, PhD, Principle Consultant, Insight Pharma Consulting, LLC, and Co-Chair, 2017 PDA Visual Inspection Forum Program Planning Committee

**Session Description:** This session begins with a case study that details the effort to implement a comprehensive program to align the visual inspection of a difficult-to-inspect product with the USP <790> requirements. The first presentation will describe the 100% inspection process, the non-destructive AQL testing, the destructive reconstituted sample AQL testing, and the AQL result trending process that was implemented. It will also discuss the incorporation of risk-based assessment of visible particulate into the assignment of AQLs, project planning and regulatory filing. The second presentation will discuss the limitations of traditional AQL-based acceptance sampling. An alternative strategy to link clinically relevant risk assessment with historical trending with the objective of detecting and responding to significant shifts in low defect levels will be presented.

8:30 a.m. – 9:00 a.m.
Case Study: Implementation of USP <790> for a Difficult-to-Inspect Product
Richard (Rick) Watson, Director, Engineering, Merck & Company/Merck Sharp & Dohme

9:00 a.m. – 9:30 a.m.
Beyond AQL Sampling: An Innovative Approach to Setting Limits for and Ensuring Conformance to Visual Defect Specifications
Elizabeth Zybczynski, Director, Risk Management, Baxter Healthcare

9:30 a.m. – 10:00 a.m.
Questions & Answers/Discussion
TUESDAY, OCTOBER 24, 2017 AGENDA (CONTINUED)

9:45 a.m. – 4:00 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall

10:45 a.m. – 12:15 p.m.
P6: Biopharmaceutical Inspection
Moderator: Deborah Shnek, PhD, President, Drug Product Development, LLC

Session Description: The first presentation will discuss a semi-quantitative method for assessing inherent visible particles with the setting of quality control limit(s). It will also include bridging studies for a second generation method. Historical inspection consistency for the first and second generation methods will also be addressed. The second presentation will address how the BioPhorum Operations Group (BPOG) has developed a “Proof of Concept” standardized methodology and tool for objectively assigning a risk value to particulates in parenteral biologics drug products. On behalf of BPOG, a summary of this methodology and its usage will be presented.

10:45 a.m. – 11:15 a.m.
Semi-Quantitative Analysis of Inherent Visible Particles for Biopharmaceutical Products
Stephen O. Krause, PhD, Director of Quality Assurance Technical Support, AstraZeneca Biologics

11:15 a.m. – 11:45 a.m.
Update on BioPhorum Operations Group (BPOG) Activities and the Particulate Risk Reduction Initiative
Shilan Motamedvaziri, PhD, Principal Engineer, Manufacturing Science & Technology, Bristol-Myers Squibb

11:45 a.m. – 12:15 p.m.
Questions & Answers/Discussion

12:15 p.m. – 1:45 p.m.
Lunch on your own. Exhibit Hall Closed – A listing of local restaurants is available at the PDA Registration Desk.

1:45 p.m. – 3:15 p.m.
P7: Primary Packaging Materials
Moderator: Thomas J. Arista, Field Investigator, Microbiological Inspections, ORA, FDA

Session Description: This session will begin with a presentation on a significant initiative to bring together executives, including CEOs and vice presidents, from biologic and pharmaceutical manufacturers with glass container and elastomeric closure suppliers to prepare industry for the complex products and manufacturing processes of the future. They aspire to achieve this through collective and collaborative continuous improvement projects to take today’s world-class injectable medicine manufacturing to the next level. The second talk will present real cases to illustrate the steps needed to keep an automated inspection machine working at optimum performance. The methodologies described in this discussion are applicable for any automated inspection machine.

1:45 p.m. – 2:15 p.m.
Enabling Reduction in Visible Particulates through Strong Industry Collaboration and Partnerships
Jennifer Johns, Director, Packaging & Device Services, Pfizer, Inc.

2:15 p.m. – 2:45 p.m.
The Reality of Commodity Variations and their Impact on Automated Visual Inspection Machines: A Case-Study Discussion of Root Cause Methodology, Understanding Limits of Automated Visual Inspection and Determining Effective Paths to Effect Meaningful Change
Robert Harding, Process Engineer, Sanofi Pasteur

2:45 p.m. – 3:15 p.m.
Questions & Answers/Discussion
TUESDAY, OCTOBER 24, 2017 AGENDA (CONTINUED)

3:15 p.m. – 4:00 p.m.
Refreshment Break, Poster Presentations and Passport Raffle in Exhibit Hall

4:00 p.m. – 5:30 p.m.
P8: Automated Inspection
Moderator: Markus Lankers, PhD, Managing Director, rap.ID GmbH

Session Description: The first talk provides an overview of a compliant approach to the implementation of a multi-staged automation inspection process. It will closely review the process design and qualification requirements to ensure that a multi-staged inspection process is implemented in a compliant manner. The second presentation will give an overall view of automated visual inspection qualification methodologies commonly used in the industry, compare these methodologies and give guidance to the audience based on their unique situations and which method may work the best.

4:00 p.m. – 4:30 p.m.
Compliant Approach to Implementation of Multi-Staged Automated Inspection
Robert Crews, Associate Director, External Quality Assurance, Merck & Company/Merck Sharp & Dohme

4:30 p.m. – 5:00 p.m.
Automated Visual Inspection (AVI) Machine Qualification Strategies
Mitsutaka Shirasaki, Senior Engineer, Genentech, Inc.

5:00 p.m. – 5:30 p.m.
Questions & Answers/Discussion

5:30 p.m.
Closing Remarks and Adjournment
Markus Lankers, PhD, Managing Director, rap.ID GmbH, and Co-Chair, 2017 PDA Visual Inspection Forum Program Planning Committee

Sponsorship and Exhibit Opportunities are Available!

High-impact, cost-effective sponsorship and exhibition packages are available for the 2017 PDA Visual Inspection Forum. Gain onsite exposure and connect with industry experts from manufacturing, engineering, packaging, process development, quality, technical services and validation. Exhibit at or sponsor this Forum to align your company with industry leaders and world-class content.

Comprehensive sponsorship packages will provide your company the opportunity to strengthen brand image, increase visibility and reinforce its commitment to the visual inspection arena. Sponsorships are available for lanyards, tote bags, notepads, pens, refreshment breaks, lunch, the Networking Reception and more.

For more information about exhibit and sponsorship opportunities, please contact:

David Hall
Tel: +1 (240) 688-4405
Email: hall@pda.org

Alison Caballero
Tel: +1 (301) 656-5900 ext. 135
Email: caballero@pda.org
CONTINUING EDUCATION INFORMATION

Continuing Education for Pharmacists

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the CPE Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

Contact Stephanie Ko via email at ko@pda.org to learn more.

Continuing Education for Engineers

PDA is an approved provider by the New Jersey State Board of Professional Engineers and Land Surveyors to offer courses to New Jersey Professional Engineers for Continuing Professional Competency (CPC) credit. Following the full participation in this course, participants will receive a Certificate of Accomplishment specifying the number of CPC credits that may be awarded. This certificate can be submitted as verification of completion to the Board for license renewal.

PDA is recognized by the North Carolina Board of Examiners for Engineers and Surveyors as an Approved Sponsor of CPC activities for Professional Engineers licensed by North Carolina. To receive a Certificate of Accomplishment specifying the number of Professional Development Hours (PDHs) that may be awarded, course participants must request the North Carolina Board of Examiners evaluation form from PDA staff. This form must be completed onsite at the conclusion of the course and returned to PDA staff.

CLASS SCHEDULE

The course will begin at 8:30 a.m. and end at 4:00 p.m. Please arrive at your course location approximately 30 minutes before the start of the course to register and receive your name badge. Please be sure to bring your confirmation letter as proof of registration during check in. PDA will not allow persons to attend a course without payment or guarantee of payment.

7:30 a.m. – 8:30 a.m.: Continental Breakfast
10:00 a.m. – 10:15 a.m.: Morning Break
12:00 p.m. – 1:00 p.m.: Lunch
2:30 p.m. – 2:45 p.m.: Afternoon Break

Students who pre-register will now be given access to electronic course notes, which may be printed approximately 1-2 weeks in advance for use during the course. Hard copies of course notes will no longer be provided to pre-registered students and only a limited number of hard copies will be available for onsite and transferring registrants on a first-come, first-served basis.
Following the 2017 PDA Visual Inspection Forum, PDA Education will hold the An Introduction to Visual Inspection course, October 25-26, at PDA’s Training and Research Institute located at: 4350 East West Highway, Suite 150, Bethesda, MD 20814.

**An Introduction to Visual Inspection**

**Location:** PDA Training and Research Institute | Bethesda, MD  
**Date:** October 25-26, 2017  
**Duration:** 2 days  
**Time:** 8:30 a.m. – 4:00 p.m.

**Course Number:** PDA #417  
**ACPE # 0116-0000-14-064-L04-P | 1.2 CEUs**  
**Type of Activity:** Knowledge

Through a combination of lecture/discussion and hands-on laboratory exercises used to develop and practice practical inspection skills, this course will cover the fundamentals of visual inspection and their application to injectable products. The skills developed through this course may be applied to both manual human inspection and automated machine inspection.

**WHO SHOULD ATTEND**

**Manufacturing:** Managers, Supervisors  |  **R&D:** Managers, Supervisors  |  **Engineers**  |  **Validation**  |  **Quality**

**LEARNING OBJECTIVES**

Upon completion of this course, you will be able to:

- Identify applicable international regulatory and compendial requirements for visual inspection
- Apply critical parameters, which must be controlled for reproducible inspection results
- Use appropriate statistical tools to assess and compare inspection methods
- Develop consistent validation strategies for visual inspection processes and equipment

**FACULTY**

**John G. Shabushnig, PhD,** Principal Consultant, *Insight Pharma Consulting, LLC*  
**Ronald Leversee,** Quality Assurance External Manufacturing, *Perrigo Company*  
**Matthew Ostrowski,** Injectable Inspection Team Leader, *Pfizer, Inc.*
2017 PDA Visual Inspection Forum
October 23-24, 2017 | Bethesda, MD
Bethesda North Marriott Hotel & Conference Center
Exhibition: October 23-24 | Course: October 25-26

Contact Information

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Business Address

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Job Title

Company

PDA Membership Number

Payment Options

All cards are charged in US$.

- By Credit Card – Clearly indicate account number, expiration date and billing address.

Total amount $________

Account Number

Exp. Date

Name (exactly as it appears on card)

Signature

Billing Address (must match credit card statement)

City

State

Zip

PDA Federal Tax I.D. #52-1906152

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice, please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancelation notice is not received by August 24, 2017, your credit card will be charged the prevailing rate. SUBSTITUTIONS: If you are unable to attend, substitutions can be made at any time, including onsite at the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee.

Group Registration: Register 4 people from the same organization as a group (at the same time) for the FORUM and receive the 5th registration free. Other discounts cannot be applied. All forms MUST be faxed in together.

Course #417
An Introduction to Visual Inspection

Course Registration | October 25-26
Please check appropriate fee (US$):

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* For this member type or discounted rate, online registration is not available and must be faxed in.

- By Check

Please make check payable to PDA and mail to:

PDA
P.O. Box 22470
Bethesda, MD 20814 USA

- By Credit Card

By Credit Card – Clearly indicate account number, expiration date and billing address. Please bill my:

- American Express
- MasterCard
- VISA

Credit Card Guarantee Only

Special Dietary Requirements (Please be specific):

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

Course Registration | October 23-24
Please check appropriate fee (US$):

- By Credit Card

By Credit Card – Clearly indicate account number, expiration date and billing address. Please bill my:

- American Express
- MasterCard
- VISA

Credit Card Guarantee Only

Special Dietary Requirements (Please be specific):

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

Please check appropriate fee (US$).

- By Check

Please make check payable to PDA and mail to:

PDA
P.O. Box 22470
Bethesda, MD 20814 USA

- By Credit Card

By Credit Card – Clearly indicate account number, expiration date and billing address. Please bill my:

- American Express
- MasterCard
- VISA

Credit Card Guarantee Only

Special Dietary Requirements (Please be specific):

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.