



World Skill Development Institute

Medical Plastics certificate course

Course Duration – 1 Year.

Plastics currently form one of the most important components of the medical industry. Medical device designers and engineers increasingly prefer plastics to conventional packaging materials such as metals owing to superior flexibility offered by plastics in fabrication process. Advancements in sterilization techniques shift towards disposable devices, development of enhanced plastic materials, and technological innovations are factors driving the overall market growth and expansion. The development of novel materials such as biocompatible polymers for use in medical implants will furthermore provide the required impetus for the global medical plastics market. Every day, plastics are involved in critical surgeries, life saving efforts, and routine medical procedures. Plastic materials can be sterilized hundreds of times without degradation. Lightweight plastics are used to form replacement joints, non surgical supports, and therapy equipment. Clear plastics provide visibility for transfusions, surgeries, and diagnostic equipment of all kinds and plastics can be machined, molded, or formed into almost any shape imaginable. The use of plastics in health care field encompasses several distinct markets. Plastic is used on a large scale as medical devices like disposable syringes, optical and dental products, heart valves, contact lenses and many more medical products. This way plastic has very importance in making medical devices. The medical plastics industry is set to expand rapidly over the next decade taking up increasing proportions of GDP, as countries provide healthcare to an ageing population, access to medicine expands in developing regions and new technology is developed.

1. PACKAGING FOR PHARMA & MEDICAL INDUSTRY

Tablets & Capsules

Liquids

Creams and Ointments

Labels

Caps & Closures

Wadding Materials

Specific New Systems

Opvc, Opp and Oriented and Non-oriented Pet Containers

Blister Trays For Ampoules, Cartridge Tubes Etc.

Single-serve/Unit Dose Packages (Laminates of PPR, Plastics and Foil)

The Delcap Metered-dose

Form, Fill, Sealing of Plastic Bottles Under Aseptic Condition

Radiation Resistant PP Bottles

Double Derker Spray-aerosol

Single Dose Blister-break Open Packs

Capped Gabletop Cartons

Refillable, Reusable and Recyclable Aerosols

Shrink Packaging and Stretch Wrapping

Bulk Drug and Fine Chemicals

Packaging of Medical Devices

Materials & Technologies

Tyvek

Dot Coat Advantages

Tyvak vs. Paper

Peelable Paper Lidding Materials

Advantages

Applications

Medical Grade Pressure Sensitive Materials

Advantages

Applications

Evoth in Health Care Packaging (HCP)

Packaging Requirements For Health Care Products

Structure, Props & Uses

Barrier Bottles/Vials

Evoth

Other Important Area of Use

Packaging & Sterility

Plastics and Their Biomedical Applications

Pharmaceutical & Medical Packaging

New Development

Packaging Waste Directive

The Directive

Conclusion

2. TESTING

Conducting Health-Based Risk Assessments of Medical Materials

Nancy Stark

Standards and Guidances

Method

Hazard Identification

Dose-Response Assessment

Exposure Assessment

Risk Characterization

Nitinol Implant

Wound-Dressing Formulation

Perchloroethylene Solvent

Ligature Material

Sources of Data

Uncertainty Factors

Safety Margins

Conclusion

Pharmaceutical

Pharmaceutical Market Focuses on Cutting Costs, Not Value

Some Segments Promising

Regulatory Requirements

Packaging Machinery

Other Trends

The Future

3. STERILIZATION

Traditional Processes

New Processes

Chemical Processes (Gas/Liquid)

Peracetic Acid

Hydrogen Peroxide

Ozone

Chlorine Dioxide

Physicochemical Processes

Plasmas

Steam

Synergetic Processes

Psoralens and UVA (PUVA)

Microwave and Bactericide

Low-Temperature Steam and Formaldehyde

Physical Processes

Microwaves

Pulsed-Light Systems

Validation of Sterilizer Processes

4. HIGH PERFORMANCE PVC COMPOUNDS & TPE™S FOR MEDICAL APPLICATION

Long Term Contribution of PVC in Health Care

Pvc™s Dominance in the Growing Market

Challenges by Environmentalist to PVC

Key Barriers to PVC Replacement

The Major Factors Which Continue to Favour the Use of PVC are

PVC Innovation

ABC of Innovation

Features of Hi-performance PVC Compounds

The Use of Hi-performance PVC in Medical Devices

TPE Based on Pvc Replaces Silicone

TPE Based on PVC Outflexes Silicone Rubber

5. INNOVATIONS REMAKE PLASTIC INJECTION MOLDING

Useful Properties

Parts on a Diet

Equipment and Processes

Automating for Success

Conclusion

6. POLYVINYL CHLORIDE IN CRITICAL HEALTHCARE PRODUCTS

Factors Which Made Polyvinyl Chloride the Material of Choice for the Fabrication of Medical Devices

Typical Medical Applications of PVC

Choice of Plasticisers

Containers for the Collection and Storage of Blood and Blood Products

Storage of Platelets

Containers for Intravenous Fluids and for Parenteral Nutrition

Containers for Constant Ambulatory Peritoneal Dialysis Solutions (Capd Bags)

Containers for the Collection and Storage of Cord Blood

Reported Deleterious Effects of Dehp Plasticised PVC and the Present Position

Trends in the Development of Newer Materials

7. ADVANCES IN MEDICAL PLASTICS

Microtagging

Thermosets

Antithrombogenic Coatings

Dryfilm Lubricant

Curing Process for Synthetic Polyisoprene Latex

Topas Cyclic Olefin Copolymer

8. MEDICAL APPLICATIONS OF POLYCARBONATE

Processing

Sterilization

Typical Applications

Renal Dialysis

Cardiac Surgery Products

Surgical Instruments

IV Connection Components

Polycarbonate Developments for the Medical Market

Radiation Grades

High-Temperature Grades

Polycarbonate Blends

Enhanced-Productivity Grades for Cleanroom Molding

Lipid-Resistant Grades

Conclusion

9. RADIO-FREQUENCY SEALING FOR DISPOSABLE MEDICAL PRODUCTS

Steve Myers

What is RF Sealing?

How RF Works

Sizing RF Sealers

Tooling

Efficient RF Sealing Techniques

Maximum Throughput With Automation

Double-cycle Sealing

Comparing RF With Other Sealing Technologies

Conclusion

10. PET BOTTLES AND APET SHEET FOR BLISTER PACKING FOR PHARMA APPLICATION

Pet Conversion Processes

Pet “ A Pure Polymer

Pet Bottles for Pharma

Filling Lines for Pet Bottles

Case Study for Use of Pet Bottles in Pharma Industry

Conclusion

Generic Drugs That Can Be Packed in Pet Bottles

Ayurvedic Products That Can Be Packed In Pet

Cost-Competitiveness of Pet Bottle for Pharma Industry

Pet Bottles for Pharma Products “ Useful Tips

Apet Sheet Material, Processing & Applications

Apet Sheets Total Consumption

Apet Thin Sheet

What is Apet Sheet

Factors For Growing Interest in Apet Sheet

Advantages of Apet Sheet

Blister Packing

Apet Sheet vs. PVC Sheet

Apet Sheet vs. PP Sheet

Gas/Moisture Barrier Properties Pet vs. Other Polymers

Salient Points of Apet Thin Sheet

Pet Ecofriendly and Recyclable

Pet Converters Expectations of Pharmaceutical Industry

Development Trials for Pharma Industry By RIL

Other Applications of Apet Thin Sheet

Conclusion

11. BREATHABLE TPE FILMS FOR MEDICAL APPLICATIONS

Barrier Films

Microclimate Dynamics

TPE Resin Chemistry

Soft Segments

Hard Segments

Film Manufacture

Lamination

Hot-Melt Screen Printing

Melt Printing

Porous Coating

Spray Coating

Medical Applications

Conclusion

12. THE CHANGING ROLE OF THE MEDICAL DEVICE CONTRACT MANUFACTURER

Growth, Growth & Growth

Outsourcing and Consolidation

Meeting the Challenge

13. MEDICAL PACKAGING

Rising Demand Predicted

Drug/Device Products Lead The Way

Cost Considerations

Test Methods

Regulatory Picture

Conclusion

14. PERFORMANCE PROPERTIES OF METALLOCENE POLYETHYLENE, EVA, AND FLEXIBLE PVC FILMS

Experimental Procedure

Results

Conclusion

15. POLYURETHANE THIN-FILM WELDING FOR MEDICAL DEVICE APPLICATIONS

Weldability of Thermoplastics

Film-joining Methods

RF Welding

Ultrasonic Welding

Direct Thermal Sealing

Induction Welding

Solvent Bonding

Conclusion

16. POLYURETHANE FILM AS AN ALTERNATIVE TO PVC AND LATEX

PVC

Natural Rubber Latex (NRL)

Thermoplastic Polyurethanes

Concerns About PVC

17. GAS PERMEABILITY AND MEDICAL FILM PRODUCTS

Materials and Experimental Methodology

Results and Discussion

Conclusion

18. OPPORTUNITIES FOR PVC REPLACEMENT IN MEDICAL SOLUTION CONTAINERS

Ethylene-vinyl Acetate

Polyester

Polyolefin Blends

Polyolefin Laminates

Functionalized Polyolefins

Conclusion

19. PRODUCING BUBBLE/TAPER TUBING FOR MEDICAL APPLICATIONS

Extrusion-line Design

Forming Considerations

Cooling and Sizing

Pulling and Cutting Systems

Conclusion

20. THERMOPLASTIC SILICONE-URETHANE COPOLYMERS : A NEW CLASS OF BIOMEDICAL ELASTOMERS

Silicones

Thermoplastic Polyurethanes

Silicone-modified Polyurethanes

Silicone-urethane Copolymers

Conclusion

21. SELECTING MATERIALS FOR MEDICAL PRODUCTS : FROM PVC TO METALLOCENE POLYOLEFINS

Fundamental Considerations

Selecting Materials

Material Performance Versus Product Performance

PVC Versus Metallocenes

Advantages of PVC

Disadvantages of PVC

Advantages of Metallocenes

Potential Metallocene Disadvantages

Challenges for Metallocene Materials

Safety and Quality

Product Design and Processing

Product Performance

Conclusion

22. COATING AND SURFACE TREATMENT TECHNOLOGIES

Ion-Beam Processingâ€™Spire Corp. (Bedford, MA).

Light-Activated Surface Modificationâ€™BSI Corp. (Eden Prairie, MN).

Plasma Surface Engineeringâ€™Talisson Research (Sunnyvale, CA).

Antimicrobial/Antibiotic Coatingsâ€™STS Biopolymers, Inc. (Henrietta, NY).

Thromboresistant (Heparin) Coatingsâ€™Baxter Healthcare Corp. (Irvine, CA).

23. INJECTION MOLDING ENGINEERING PLASTICS

How It Works

Balancing Variables

Tool Design

Design Aids

Conclusion

24. GROWTH AND NEW CHALLENGES FOR DEVICE MARKET

Cost Concerns

Steady Growth

Regulatory Issues

Technology Issues

The Future

25. ASSESSING THE PERFORMANCE AND SUITABILITY OF PARYLENE COATING

Medical Coating Characteristics

Medical Coating Applications

Parylene Review

Parylene N

Parylene C

Parylene D

The Parylene Process

Conclusion

26. PAPER OR PLASTIC? MEDICAL NONWOVEN COMBINES BEST PROPERTIES OF BOTH TAPES

Thin-Film Coater Improves Process Control

Susan Wallace

Chips Propel Advances in Medical Imaging Equipment

Susan Wallace

27. PRODUCTS & SERVICES

Dispensing units

Slot-die system

Packaging system

Tube cutter

Automation equipment

Injection moulding machines

Catheter processing equipment

Benchtop moulder

28. REPROCESSING DISPOSABLE (SINGLE-USE) ITEMS

Background

How Safe Is Reprocessing

Benefits of Reprocessing

Definitions

Recycling

Reprocessing

Reprocessing Disposable (Single-use) Items

Reprocessing Disposable Surgical Gloves

Recycling or Reprocessing Disposable (Plastic) Syringes Andhypodermic Needles

Recycling Disposable Syringes

Reprocessing Disposable Syringes (and Needles)

Reprocessing Versus Disposal of Needles and Syringes

29. PLASTICS MEDICAL DISPOSABLES & AMPULE TRAYS WITH G.N. PRESSURE-FORMING TECHNOLOGY

Introduction

Ampule Package

Current Technology

Contact Heat, Cut-in-place, Pressure Thermoforming Technology

Quality Control

Flexibility

Efficiency

Simplicity

Applications of Contact Heat, Cut-in-place, Pressure Thermoformers

Design of Parts

Material

Production Volume

Cost

30. PVC IN MEDICAL APPLICATION

Introduction

Topic of Discussion

Medical Application For PVC

Benefits of PVC

Safety

Chemical Stability

Biocompatibility

Clarity & Transparency

Flexibility, Durability & Dependability

Sterilizability

Compatibility

Resistance to Chemical Stress Cracking

Low Cost

Additives Used for PVC Compounding

Plasticisers

Stabilisers

PVC In Medical Products – An Environmental Perspective

Regulation and Product Standards

Good Manufacturing Practice (GMP)

Important Aspects Of GMP

Plastic Processing in Clean Rooms

I.V. Fluid Containers: Why PVC?

Cost Effectiveness

Reliability

Simplicity in the Filling Process

Safety in the Hospital

WMSDi