John F. Cuspilich

Quality Assurance, GMP/QMS Specialist, Auditor, Instructor & Remediation SME

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Management of Quality Assurance, GxP audits, training, GMP / QMS facilitation, and remediation projects with over 35 years, hands-on technical and management level experience within Pharmaceutical, Biotechnology, Medical Device, Validation, Dietary Supplements and regulated industries worldwide John has assisted companies in meeting stringent regulatory and quality objectives.

Assisted with guiding global companies in preparing for FDA, EU, Canadian, WHO, NMPA, PMDA, GMP/GLP/GCP/GCLP and QSR Audits. Serving various business units within Quality Assurance / Regulatory Affairs, Training, Clinical, Laboratories, Drug Development, Manufacturing, Logistics, Engineering, Technical Departments.

Assisted start-ups and established companies in meeting and exceeding FDA & Global regulatory compliance, pertaining to 'for-cause' or 'due-diligence' remediation. Assisting companies to achieve, resolve, remediate and exceed regulated requirements, mandates, with the technique of promoting GxP standards and practices through template development, and interactive hands-on training. Global traveling with 10year Chinese and India VISAs.

- ***CGMP – QMS – GCP – GLCP – GLP – GVP – 21 CFR PART 11 – QSR – ISO 13485 SME***
- ***Execution of Turn-Key GMP and QMS*** processes, *procedures, and infrastructure for start-ups and existing companies. Challenging Quality Management Systems for regulatory readiness.*
- ***Gap Analysis of Existing QMS GMP Compliance Standards – New Standards Implementation***

Extensive knowledge in industry regulations and standards; U.S. FDA (CDER (DEA), CBER, CDRH, CVM, CFSAN), CGMP, GLP, ICH, EU EMA GMPs & Directives, OECD, GAMP, ISO, NMPA (China), PMDA JPAL (Japan), OSHA, HHS, EPA and GCP regulations and thorough knowledge in the process of implementation of these standards. John enjoys speaking and engaging at many of the industry professional associations, seminars, and trade shows worldwide, conducting both on-site and off-site training seminars, and speaking engagements."

Pharmaceutical, Medical Device, Clinical, Biologics, Dietary & Cosmetics Audits Gap Analysis:
Develop, challenge and execute audit plans for global on-site or remote Audits for Vendors/Suppliers, CMOs, CDMOs, CROs, for Manufacturing and Clinical Internal Departments. Development of Gap Analysis project plans to support the regulated industry,

- *Pharmaceutical, APIs, Excipients, Controlled Substance, Biologics, Blood, Cell, Tissue, 503B*
- *Laboratories, and Analytical Services – Stabilities – GMP/GCP/GCLP*
- *Dietary Supplements – Retail Market Certifications*
- *Cosmetics – Therapeutic and nontherapeutic*

Medical Device Quality Systems Regulations and Quality Management Systems. *Assisting companies to meet U.S. CDRH requirements, ISO 13485 and E.U. 2017/745 Medical Device Regulations.* ***Combination Devices*** *for Pharmaceutical or Biologics. PMA / 510(k). Mock CDRH Audits and Gap Analysis (ISO 13485)*

Good Clinical Practice and Good Clinical Laboratory Practice Auditor, Trainer and Monitoring SME.
GCP Auditor – Quality Assurance Oversight, and Project Management. Investigational Products in accordance with CGMPs for Phase 1, Investigator Site Audits, Regulatory Affairs and Safety, Database and DM Audits, eDC Systems and Clinical Monitoring activities supporting Human and Veterinary Studies.

Process, Equipment, Facilities, Systems & Software Qualification, Validation Expertise:
Extensive Process, Equipment, Systems, Device, Computer systems, and Software Validation and GXP Audit experience for the Regulated Industry. Work in support of Good Validation Practice Standards.

GMP – GLP – GCP – ISO 13485 Training Program Director and Gap Analysis Auditor for Training:
John also conducts numerous conferences and seminars on Good Manufacturing Practice (GMPs), Quality Management Systems (QMS), Computer Systems Validation and 21 CFR Part 11 Compliance requirements.

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Current Work History Summary:
The Auditing Group, Inc. & GXP Services (The Validation Group & GMP Boot Camps)

2002 – Present – Quality Assurance, Regulatory Affairs, Sr. Auditor and Remediation SME:

Management, development and implementation of Good Manufacturing Practice (GMP) and Quality Management Systems (QMS) for small to medium size companies, with full turn-key templates, procedures, QMS processes, and training ensuring regulatory and quality compliance readiness. Management of Global Quality Assurance and GxP Audit Teams supporting internal Audits, Vendor and Supplier Audits, preparing Client/Customer audits and Agency Regulatory Audits, U.S. FDA, (CDER, CBER and CDRH), Health Canada, EMA, WHO, PMDA, NMPA, etc., supporting 'Due-diligence' and/or 'For-cause' audits. Conduct of Mock audits and Gap Analysis remediation projects.
Global Remediation Projects, Drug Development, Clinical Preparation, and Mock Agency Audits.
Gantt Driven Audit and Quality Management Systems Development and Project Management.
Implementation of Quality Management Systems Components.

○ CAPA	○ Nonconformance	○ Deviations	○ Change Controls
○ Complaints	○ OOS / OOTs	○ Audits	○ Risk Management
○ Training	○ Recalls/Returns	○ 21 CFR Part 11	○ Validation

VISAs: **China** 10-year **India** 10-year

- Quality Assurance, Regulatory Affairs, and Sr. Audit Specialist supporting GMP, GLP, GCP, QMS, ICH, ISO, & WHO Audit and Remediation Consulting (2400+ compliance audits, training and remediation projects) Supporting Drug, Biologics, Medical Device and Combination Devices. Pharmaceuticals for Commercialization, Feasibility and Clinical Trials.
    - Pharmaceutical Drug Manufacturing, Drug Substance and Drug Products, APIs, Controlled Substance, CAPA, Deviations, Nonconformance, OOS/OOT, Change
    - Medical Device Audits SME – 21 CFR Part 820 QSR, Mock FDA CDRH Audits, EU MDR 2017/745, QMS Remediation – ISO 13485:2016 and Combination Devices.
    - 3rd Party Contract Forensics – Supporting FDA CDER, CBER and CDRH Divisions.
    - Clinical Research Organizations (CROs), Site Investigations, eDC/DM, Biostatistics
    - Manufacturing, Research & Development, Clinical, Medical Device, Laboratories
    - Vendors & Suppliers, Consultants & Contract Manufacturer Audits
    - Audits for Bio-Pharma OTC, Ethical, Radiopharmaceuticals, Nutraceuticals, Bulk API
    - Supporting – US FDA, EU EMA, SFDA (NMPA), TGA, and WHO Audits
    - Manufacturing, API, CMO, CPO, CAO, Warehouse and Distribution Audits
    - Laboratories in support of GMP and / or GCP Activities
- Quality Management Systems (QMS) Audit, Gap Analysis, and Remediation
- Validation Audits and Gap Analysis (Process, Facility & Equipment) Auditing Services
- Quality Auditor – Process, Manufacturing, and Analytical Equipment, LIMs, EDC, Clinical Data Management, SAE, AER, PLC, SCADA, etc.
- Engineering (Design / Build Facility Audits), Maintenance and Technical Compliance Audits
- FDA Assisted Audits, PAI, Pre-FDA Inspection Audits and Clinical Trial Audits
- Employee HR / Investigator Audits and Investigations (CV Audits)
- Technical review and development of the Code of Federal Regulations publications for The Government Printing Office, Washington, DC. GMP Publications, Inc.

Partial List of Clients available upon request

The Validation Group, LLC.
2002 – Present
Senior Validation Specialist:
Managed, coordinate and conducted full validation services supporting Pharmaceutical, Medical Device, Biologics and Laboratory Equipment, Software and Systems, Cosmetics, Dietary Supplements, and Regulated Industries. Support Validation Activities required by ISO Compliance.
Full Gantt driven task management.

- Validation Services – Development of Validation Protocols – Contract Developer
    - Facilities Commissioning and Qualifications – Basis of Designs
    - Equipment – Process and Utilities
    - Process Validation Services
    - Software and Computerized Systems (21 CFR Part 11)
    - Analytical Methods
    - Cleaning Validation Services
    - Distribution and Logistics

GMP Boot Camp Training and GXP Conferences, Inc.
2002 – Present
Senior Instructor:

- Conducted over 420 instructional webinars
- Conduct of over 200 on-site GMP, QMS, QSR, ISO, 21 CFR Part 11 Electronic Systems, GLP and GCP Training Seminars
- Training and Development – Customized training packages and presentations:
    - 21 CFR Parts 210/211 Drug GMPs – The Basics 101 / The Basics 102, Pharmaceuticals – Finished and APIs – ICH Q7 GMPs for Active Pharmaceutical Ingredients
    - 21 CFR Parts 11 – Electronic Records; Electronic Signatures
    - 21 CFR Parts 820 – Quality Systems Regulations
    - 21 CFR Part 58 – Good Laboratory Practice – Toxicology & Non-Toxicology – OECD GLP, GCLP and Laboratory Controls supporting manufacturing processes.
    - Cosmetic GMPs
    - Dietary Supplements under 21 CFR Part 111 and Predicate Rules
    - Software and Systems Development Compliance Requirements under 21 CFR Part 11
    - Validation and Qualification – The Basics 101
    - Validation and Qualification – The Basics 102
    - Risk Management
    - Combination Devices
    - Quality Management Systems Gap Analysis Auditing Training
    - ISO 9001 – Quality Management Systems and Quality Process
    - ISO 13485 Quality Management
    - ISO 14971 Risk Management
    - EU GMPs 1-9 – EU GMPs Annex 1-20
    - Chinese Decrees 79 (and 64), US GMPs 21 CFR Parts 210/211 and EU GMPs Chapters 1-9
- Hosted of Domestic GMP Conferences
    - Pharmaceutical cGMPs (US, EU and ICH Q7)
    - Medical Device GMPs and the QMS (US and ISO 13485)
    - Combination Devices (Drug and Device)
    - Validation and Qualification

Partial List of Clients available upon request

1998 to February 2004: SCIREX Clinical Research Organization (CRO)
Title: Associate Director Quality Assurance and Senior Quality Auditor

Roles and Responsibilities – Sponsor, Vendor, Supplier, Site, DMS, Statistics, SME and Auditor, Associate Director Quality Assurance / Regulatory Affairs – Good Clinical Practices in accordance with US and EU Regulatory Requirements. Supporting IP and Clinical processes, GMP, GLP, Part 11 Electronic Records; Electronic Signatures, Drug Development cGMP for Phase 1 and Medical Devices for Clinical.

Duties: Conducted over **300** GCP, GCLP, GLP, and GMP Audits supporting Global Clinical Trials in all aspects of clinical activities, IND, NDA/ANDA/Orphan, BLA, PMA/510k. Included but not limited to:

- Develop, Implement, Manage and Conducted SCIREX Internal, Sponsor, Supplier and Vendor audits pertaining to IT, Validation, GMP, GLP, ICH, 21 CFR Part 11 and Facility Compliance. Conducted internal personnel, Sponsors, and Vendor training in Good Auditing Practices, 21 CFR Part 11, Good Validation Practice and Techniques, Quality Systems Regulations (Part 820), Good Programming Standards and Practices, etc.…
- Conducted Government Sponsored Clinical Training for the Institute for Clinical Research India (ICRI)
- Senior Auditing Responsibilities – Development Audit Standards for;
    - Sponsor and CRO Audits
    - Auditing of Investigator Sites, Investigators, Financial Disclosure and State Board Certifications
    - IRB Audits
    - Informed Consent form reviews
    - Monitors and Clinical Supervisory Personnel
    - Auditing Sponsor's Vendors and Suppliers
    - Database Audits (Database Management Systems)
    - Biostatistical Audits
    - SAE/AE/AR Filing Audits
    - MedWatch and Product Safety Audits
    - FDA Assisted Audits, Do-Diligence, For-Cause, and Clinical Trial Approval Audits
    - Acting as 3rd. party auditors for Sponsor Contracts
    - Acting as 3rd. party auditors for FDA Assisted Audits
- Training Curriculums - Good Clinical Practice (GCP) / Good Clinical Laboratory Practice (GCLP)
- Development, training and execution of the Corporate Validation Standards and Policies
- Development, training and management of the Corporate Validation Steering Committee
- Implementation of the Corporate Computer Systems Validation Guidelines for multiple sites
- Developed the Steering Committee 21 CFR Part 11 Charter, Validation Master and Project Plans
- Coordinated the Validation efforts utilizing in-house technicians and Contractors
- Developed the Global Computer Systems and Application Inventories
- Published SOPs outlining Validation activities, SDLC process and individual tasks
- Based on the verified inventory, implemented the Gap Analysis process which determined the components of the inventory items and requirements.
- Based on the verified inventory, implemented the risk analysis and assessment process, which determined the level of validation, qualification or verification required.
- Developed the project timelines (based on risk assessments and needs), using various validated or qualified tools such as MS Project Gantts, databases and 3rd. party software, i.e. Trackwise, Software Magic, Track-it and others.
- Developed individual Software Systems and Application validation protocols (see http://www.validations.com for additional validation effort details)
- Implemented IT, development and service support SOPs
- Developed Maintenance, IT Support and Systems or Application retirement plans
- GMP, GLP, ICH & GCP Auditing

1994 – 1999 Sentry Technologies, Inc.
Auditing Services (Pharmaceuticals, Medical Devices, Biologics, Dietary Supplements, Cosmetics)
Title: Senior Auditor / Developer / Senior Consultant (GMP – GCP – GLP – Systems)

Compliance Auditor / Engineer – Asset Auditor, Validation, Engineering, Application & Development Contract Engineering Services – Development, Systems Implementation and Validation Projects. Technical services and support consultant - **Merck**, **Novartis**, **SKB**, **Bayer**, **Sterling Pharmaceuticals**, GMP Institute, Johnson & Johnson, McNeil Consumer, The Validation Group, Judge, Integrated Project Services, etc

- **Sentry 2000 Quality Management Software and Auditing System**
- Sentry 2000 Pharmaceutical Compliance Software System
- Sentry 2000 Calibration Management System
- Sentry 2000 Work Order Management System
- OEM 2000 Equipment Management Software for Vendors and Suppliers
- Bio-Pharm 2000 Software for Inventory Management - CMOs

Management of over 680 Quality Management Systems (QMS) installations world-wide.

- Development and Implementation of the first MS Windows based Quality Management Software System – Sentry 2000 Quality Management System.
- Validation Services – Development of Validation Protocols – Contract Developer
    - Validation Master Plan Development
    - Project Plan Development;
        - User requirements;
        - Functional requirements;
        - Matrix Development;
    - Design qualifications (DQ)
    - I/O Verifications and Qualifications
    - Integration Qualifications
        - Bespoke Applications
        - COTS Applications
        - SaaS Applications
    - Installation qualifications (IQ)
    - Operational qualifications (OQ)
    - Performance qualifications (PQ)
- Supporting, but not limited to:
    - Spreadsheets – Microsoft Excel, Microsoft Lists, Google Lists,
    - Databases – Robust and Non-Robust
    - Quality Management Systems (QMS)
    - Maintenance, Calibration & Engineering Management Software
    - Laboratory Information Management Systems – Equipment Software
    - Document Management Software and Systems
    - Inventory Management Software - Enterprise resource planning (ERP) Software
    - Financial and Business Software
    - SaaS, IaaS, PaaS, Systems and 3rd Party Software Products
    - EMAIL and Text Messaging Software Systems
- Development, implementation and validation of Maintenance, Material Management, SCADA, DCS, PLC, Compliance and Engineering software applications and systems
- Auditing Services for Asset and Compliance Management
- Development and Validation of Inventory Systems for Asset Control Systems
- Engineering, Design/Build, Maintenance and Technical CAD Services
- Turn-key Process, Equipment and Software Validation Services
- Laboratory Design / Build Project Management
- Laboratory Equipment Validation:

1989 – 1995: Sterling Pharmaceuticals - Bayer Pharmaceuticals – Integrated Project Services (IPS)
Title: Manager of Engineering Auditing and Technical Services contracted to Sterling Pharmaceuticals

Duties: Direct, Audit, Maintained and Design/build responsibilities for Sterling Pharmaceuticals NJ R&D, & PA Manufacturing Facility. Managed in-house and contract technical staff. Developed SOPs, Validation Protocols and Project Plans. Maintained Process, Utilities and Facility Equipment. Development of Equipment specifications, Purchasing, and Validation of all Facility, Utility & Process Equipment and Systems:

- Developed and Managed the Sterling 2000 Quality Management Software System
- Computer Systems, SCADA, DCS and PLC, validation protocols including VMP, IQ, and OQ
- Network and Desktop Validation Protocols including VMP, IQ, and OQ
- Analytical Equipment, Spectrophotometers, Samplers/Injectors, Pumps, Assay Equipment, etc.
- Fluid Bed, Tray and Static Dryers, Mixers, Blenders & Sifters/Screeners
- Steam Systems, Process & Utility, Water Systems, Process & Utility Washers, Sterilizers, Autoclaves
- Electrical Systems and Power Generating Equipment
- Tablet Manufacturing Equipment – Presses, Coaters, Sorters, Counters, Fillers & Gel Equipment
- Environmental Equipment – HVAC, Environmental Chambers, Stability Chambers and Freezers
- Packaging Equipment, Lab Equipment, Manufacturing Equipment
- Development of Corporate Validation Standards for Process, Packaging, and Facility Equipment, Systems and Applications.
- Clean-in-Place, Sterilize-In-Place, and Clean Room Process Cleaning validation.
- Developed Corporate standards (Eastman Kodak, Sanofi and Sterling Pharmaceuticals) for OSHA 1910.143, EPA Response, HAZMAT First Responder, Inventory Controls, and Engineering

1985 – 1989: Purolite
Title: Engineering and Mechanical Services Director / Manager US
Technical Consultant – UK
Duties: Chief Engineer – **Senior ISO Auditor – Woodward Clyde** - Construction and Maintenance.

- Oversee Engineering and Technical Services supporting the design/build of Chemical Manufacturing facilities in the United States and Pontyclun, Wales, UK. Both Class 1/Div 1/2 facilities.
- Supervised over 18 in-house technicians and engineers, and over 400 contract trades, Pipefitters, Welders, Demolition, Electricians, Software and Instrumentation Contractors, Cleaning Services and other trades.
- Installation of Reactors, Low- and High-Pressure Boilers, Tanks, Vessels, Dryers, Packaging Lines and Distribution Centers.
- ISO Audits and Preparation for ISO 9001 Certifications
    - Development of ISO preparation documentation, services and procedures.
    - Development of Quality Assurance initiatives in support of ISO Certifications.
- Managed 18+ Technical Service Personnel, 3 Engineers and 400+ Trades.
- Design / Build & CAD Engineering Services
- Pipefitting, Millwright, Welding, Electrical/Electronics, Steam and Water Systems, PLC, DCS, SCADA
- Fire Remediation after devastated fire destroyed plant – Design and rebuilt $80 Million Ion Exchange Resin Manufacturing Facility.

1977 – 1984: U.S. Navy
Title: Propulsion Engineer – EN5
A-Gang Team Lead – Multi-discipline Resource Management

Duties:

- Engineman – Mechanical Technician
- Hull-Tech Welding Lead – Underwater Spot Welder Certificate
- Boiler Technician – High Pressure 1200PSI Plant
- Coxswain – Boat Captain, Small Craft
- Fireman – Lead Fireman Captain
- Repel Boarders – Firearms Specialist – Active Shooter Training

Education

- Conducted and attended over 400 GMP/QMS Training Sessions with over 6300+ hours
- Eastern Illinois State University Great Lakes Institute of Technology – **AS Propulsion Engineering 1978** – 1980 – US Naval Contract.
- US Navy Propulsion Engineering. Damage control, Firefighting and HAZMAT training. 1978 – 1980
- Drexel University, PA. – Architectural Design - 1985 - 1986
- Burlington County College - Mechanical Engineering – Computer Sciences – AutoCAD release 11/2000 (Non-degreed)
- Burlington County College – Computer Sciences - Computer Programming/Visual Basic programming (Non-degreed)
- US Navy – A Schools
    - Propulsion Engineering,
    - Welder, Hull Technician Certificate
    - Boiler Technician 1200PSI Certificate
    - Engineer SME
    - Small Arms Training – Repel Boarders Training – Active Shooter Training
    - Fireman – Firefighting Training – EMS Training
- ISO Registrar Training, Purolite, PA - Woodward Clyde
- Good Manufacturing Practice – Full training package (North East Branch Rep for GMP Institute)
- DIA Good Clinical Practices – GCP
- PDA Auditor – Tri-Auditors
- ASQ – Certified Quality Auditing Course 1998 – 1999 Temple University
- ASQ – Certified Quality Engineering Course 1998 – 1999 Temple University
- Training seminars, GMPs, Part 11, Clinical, Auditing, GLPs, ISO, etc…
- Pipefitters Apprenticeship Program apprenticeship training program. IAM Local 9
- Star Technical Institute Electronics and Robotics – 18 month program.
- Lyons Technical Institute AC&R – 10 month program
- Engineering NJ Blue Seal,
- PA Engineers 'A' Licenses
- Welder Training and Testing Institute (WTTI) – 10 month program
- Woodward Clyde Environmental EPA 165 40 hour EPA certified HAZMAT First Responder Course
- Borland Team B Specialist Training

Licenses, Certificates, Publications and Achievements

- Over 6300+ hours cGXP Training supporting Bio-Pharmaceutical, Medical Device, Cosmetics, Combination Devices, 503B, FDA, DEA, CDC, ISO, EMA, and Dietary Supplements.
- Managing Editor – GXPNews
- Managing Editor and Quality Assurance for Government Printing Office – GMP Publications.
    - Proof reading of new regulations pertaining to 21 Code of Federal Regulations
    - Supporting the GPO in corrections and updating of the Code of Federal Regulations pertaining to 21 Code of Federal Regulations
- Authored - Published:
    - Computer Systems Validation Guideline for Industry, published 8/2000
    - The Auditor's Master Handbook 2005 GMP Publications
    - 21 CFR Part 11 Auditor's Check List 2005 GMP Publications
    - 21 CFR Part 210/211 GMP Auditor's Check List 2007 GMP Publications
    - 21 CFR Part 820 / ISO 13485 Quality Systems Auditor's Check List GMP Publications
    - Active Pharmaceutical Ingredients (ICH Q7) Auditor's Check List 2012 GMP Publications
    - 21 CFR Part 111 Companion's Guide, GMP Publications
- Authored the SENTRY 2000 cGMP Facility Management Software
- Web site author of GMP Publications, Inc. http://www.gmppublications.com
- Web site author The Auditing Group, Inc. & Validations.com
- Web site author CAPA Manager (capamanager.com)
- Web site author of FDA.COM and Managing Editor / Discussions Coordinator http://www.fda.com
- Authored the OEM Management System for Windows
- Registrar ISO Auditor Training – Woodward Clyde Engineering and Consulting Group
- GMP Training – GLP Training
- GMP Train the Trainer – GMP Institute

- GERM, Tri-Auditor Course, LIMS Management
- Conducted numerous training seminars and conferences on GMPs, Mutual Global Harmonization and 21 CFR Part 11 Implementation and Site Remediation
- Member of the GPO Review Board
- ISPE Active Member and Management of the ISPE Delaware Valley Chapter Web site 1998-2000
- DIA Active Member
    - GERM Course Instructor 2005
- PDA Active Member
    - Tri-Auditor's Course 2004/2005/2006
- ASQ Active Member
    - ASQ CQE – Course – Temple University 1998 – 1999
    - ASQ CQA Course – Temple University 1998 – 1999
- RAPs Active Member
- AASP Active Member
- Borland Developers Licensing partnership group – Team B Specialist
- Microsoft Level 2 and Sun Developers Group
- cGMP, FDA and OSHA compliance audit seminars (GMP Institute)
- Written and conducted in-house fire, OSHA safety training and HAZMAT clean-up response training procedures
- NJ EPA Certified 165.15 & 29 CFR 1910.120 Hazardous Waste Operations and Emergency Response
- Written and conducted Confined Space Entry and Safety Tag & Lock out seminars, procedures and SOPs
- Wrote the Eastman Kodak/Sterling Winthrop Safety Lockout Corporate Manual
- Certified Yale fork truck training instructor
- Red Cross First aid training
- NJ State Blue Seal Engineering and Pa. Engineering A license
- NJ State Blue Seal and Pa. Engineering 'A' Steam Boiler operations instructor.
- U.S. Navy – Cold War Service Medal
- U.S. Navy – Efficiency Conflict Medal

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