

(b) (6)	DAVID R KIMES DVP QUALITY ASSURANCE	(b) (6)
Location: Lake County Division: ADD-Diagnostics		Manager: (b) (6)

Education

Institution	YOUNGSTOWN STATE UNIV, OH	Program	Chemistry
Graduation Date	Jun 1, 1983	Education Level	Bachelor's Degree (± 16 years)

Work Experience through present

Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	DVP GLOBAL QUALITY ASSURANCE - ADD - LAKE COUNTY
Start Date	Sep 1, 2014	End Date	Present (1 month)
Supervisor's Name	(b) (6)	Supervisor's Title	(b) (6)
May we contact the supervisor?	Yes	Major Responsibilities and Accomplishments	
Responsible for Abbott Diagnostics Quality and Compliance, including operations, quality systems and design quality.			

Employer	ABBOTT	Job Family - Not required. Please complete more detailed job title information below.	DVP GLOBAL QUALITY ASSURANCE - ADD - LAKE COUNTY
Start Date	Sep 16, 2013	End Date	Aug 31, 2014 (11 months)
Supervisor's Name	(b) (6)	Supervisor's Title	(b) (6)
May we contact the supervisor?	Yes	Major Responsibilities and Accomplishments	
Responsible for global operations quality, compliance & product quality assurance over 7 Abbott Diagnostic manufacturing locations globally (US and Europe).			

Start Date	Nov 1, 2010	Job Family - Not required. Please complete more detailed job title information below.	SR DIR QUALITY - AMD - DES PLAINES
Supervisor's Name	(b) (6)	End Date	Sep 16, 2013 (2 years 10 months)
May we contact the supervisor?	Yes	Supervisor's Title	(b) (6)
Major Responsibilities and Accomplishments			
Responsible for global quality and compliance for Abbott Molecular, implemented BEx (Lean/Six Sigma) to improve efficiency as part of continuous process improvement initiatives. Improved compliance profile while reducing impact of poor costs of quality.			

Employer	Abbott Diagnostics
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Start Date	Sep 15, 2008	Job Family - Not required. Please complete more detailed job title information below.	SR DIR STRATEGIC QUALITY - ADD - ABBOTT PARK
Supervisor's Name	(b) (6)		
May we contact the supervisor?	Yes	End Date	Oct 29, 2010 (2 years 1 month)
		Supervisor's Title	(b) (6)
Major Responsibilities and Accomplishments			
Lead quality professional for the transfer of 33 products (FDA PMA & 510k) from the US to Europe. Four European sites were successfully registered with FDA, with approval upon 1st inspection. Additionally, 41 PMA & 510k products were transferred from Puerto Rico to Lake County, IL.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	DIR LC OPS QUALITY - ADD - ABBOTT PARK
Start Date	Jun 15, 2006		
Supervisor's Name	(b) (6)	End Date	Aug 15, 2008 (2 years 2 months)
May we contact the supervisor?	Yes	Supervisor's Title	(b) (6)
Major Responsibilities and Accomplishments			
Quality Head for the Lake County manufacturing site supporting entire product life cycle. Working with operations peers improved compliance profile while improving product availability to best in class standards of >>99%.			
Employer	Abbott Diagnostcs	Job Family - Not required. Please complete more detailed job title information below.	DIR LC QUALITY SYSTEMS - ADD - ABBOTT PARK
Start Date	Apr 15, 2005		
Supervisor's Name	(b) (6)	End Date	Jun 15, 2006 (1 year 2 months)
May we contact the supervisor?	Yes	Supervisor's Title	(b) (6)
Major Responsibilities and Accomplishments			
Responsible for the adequacy, suitability and effectiveness of the ADD Lake Coutny, Illinois QS. Achieved ISO 13485:2003 certification upon initial audit by Notified Body. Implemented improvements to key QS and implemented Business Excellence (Lean/Six Sigma) in the Quality organization.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	MGR LC SITE QUALITY SYSTEMS - ADD - ABBOTT PARK
Start Date	Jul 15, 2004		
Supervisor's Name	(b) (6)	End Date	Mar 15, 2005 (8 months)
May we contact the supervisor?	Yes	Supervisor's Title	(b) (6)
Major Responsibilities and Accomplishments			
See Director LC QS above			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	MGR PRODUCT QUALITY - ADD - ABBOTT PARK
Start Date	Sep 15, 2002		
Supervisor's Name	(b) (6)	End Date	Jun 15, 2004 (1 year 9 months)
May we contact the supervisor?	Yes	Supervisor's Title	Not Specified
Major Responsibilities and Accomplishments			
As part of restructuring, implemented Product Quality Assurance function to support global product monitoring post market oversight. Consolidated complaint and stability testing into a single function and managed area. Redefined CAPA process based on Six Sigma MAIC process. Trained organization and provided project management support of CAPA investigations. Elements of the model were deployed across corporation.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete	DIV MGR QUALITY SYSTEMS - ADD - ABBOTT PARK

Start Date	Apr 15, 2001	more detailed job title information below.	
Supervisor's Name	(b) (6)	End Date	Aug 15, 2002 (1 year 4 months)
May we contact the supervisor?	Yes	Supervisor's Title	Not Specified
Major Responsibilities and Accomplishments			
Responsibilities included oversight of Division quality systems. Provided post market risk management assessment and CAPA support across global operating sites. Provided division metrics to support management review, developed IT system to support metrics roll-up. Re-engineered the laboratory investigation process to ensure alignment with regulatory guidance/expectations.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	QUALITY MGR LEVEL 1 - ADD - ABBOTT PARK
Start Date	Jul 15, 1999	End Date	Apr 15, 2001 (1 year 9 months)
Supervisor's Name	(b) (6)	Supervisor's Title	(b) (6)
May we contact the supervisor?	Yes	Major Responsibilities and Accomplishments	
Managed the Hepatitis Quality Unit supporting design, operations and on-market activities. Quality lead for MRB and developed statistical process control procedures and SW application to monitor test method performance.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	PRODUCT GROUP QUALITY MGR - ADD - ABBOTT PARK
Start Date	Feb 15, 1999	End Date	Jul 15, 1999 (5 months)
Supervisor's Name	(b) (6)	Supervisor's Title	Not Specified
May we contact the supervisor?	Yes	Major Responsibilities and Accomplishments	
Managed validation quality organization, participated in team which aligned the ADD validation process with ICH guidance.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	MGR MFG QUALITY OPS - ADD - ABBOTT PARK
Start Date	Sep 15, 1995	End Date	Jan 15, 1999 (3 years 4 months)
Supervisor's Name	(b) (6)	Supervisor's Title	Not Specified
May we contact the supervisor?	Yes	Major Responsibilities and Accomplishments	
Section Manager for the Hepatitis Quality Unit. Supported design control, operations and on-market activities. Implemented on-market stability monitoring program.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	SR RESEARCH BIOCHEMIST - ADD - ABBOTT PARK
Start Date	May 15, 1990	End Date	Sep 15, 1995 (5 years 4 months)
Supervisor's Name	(b) (6)	Supervisor's Title	Not Specified
May we contact the supervisor?	Yes	Major Responsibilities and Accomplishments	
Participated in the development of hepatitis immuno-assays and transfer to operations as part of the AxSYM system. Products were transferred from R&D in US to Germany and Japan on time with the systems launch.			
Employer	Abbott Diagnostics	Job Family - Not required. Please complete more detailed job title information below.	SRTECHNICIAN AQA - ADD - ABBOTT PARK
Start Date	May 15, 1988	End Date	May 15, 1990 (2 years)
Supervisor's Name	(b) (6)	Supervisor's Title	Not Specified
May we contact the supervisor?	Yes	Major Responsibilities and Accomplishments	

Major Responsibilities and Accomplishments

Performed in process and final release testing for Hep/Retro products. Implemented & validated test methods for PAGE Electrophoresis and Western Blot.

Employer	NO. IL POLICE CRIME LABORATORY	Job Family - Not required. Please complete more detailed job title information below.	FORENSIC SCIENTIST - HIGHLAND PARK
Start Date	Jul 15, 1983	End Date	Apr 15, 1988 (4 years 9 months)
Supervisor's Name	(b) (6)	Supervisor's Title	Not Specified
May we contact the supervisor?	No		

Major Responsibilities and Accomplishments

Performed analytical, serological, toxicological and chemical analysis of forensic evidence using a broad range of analytical equipment and methods. Generated reports of findings and testified in courts of law as an expert witness.

Employer	TRI STATE LABORATORIES	Job Family - Not required. Please complete more detailed job title information below.	FORENSIC SCIENTIST - NILES
Start Date	Dec 15, 1981	End Date	Jun 15, 1983 (1 year 6 months)
Supervisor's Name	Not Specified	Supervisor's Title	Not Specified
May we contact the supervisor?	Yes		

Major Responsibilities and Accomplishments

Performed analytical, serological, toxicological and chemical analysis of forensic evidence using a broad range of analytical equipment and methods. Generated reports of findings and testified in courts of law as an expert witness.

Certifications

Certification	ASQ CMQ/OE	Location	Not Specified
Expiration Date	Jun 30, 2016	Issue Date	Mar 6, 2004