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| [Screen 0](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=1_C_1)  [1\_C\_1](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=1_C_1) | Product Quality Complaint and Adverse Event Reporting at Abbott  Click the forward arrow. |  |
| [Screen 1](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=2_C_2)  [2\_C\_2](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=2_C_2) | We do business the right way, by making ethical and compliant decisions in connection with our work.  Abbott is dedicated to improving healthcare by providing high-quality, safe, and effective products and ensuring compliance. |  |
| [Screen 2](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=3_C_3)  [3\_C\_3](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=3_C_3) | Upon the completion of this course, you will be able to:   * Know what a product quality complaint is. * Know what an adverse event is. * Identify a product quality complaint and adverse event. * Know how and when to report a product quality complaint and adverse event. * Know where to go for help and to get support. |  |
| [Screen 3](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=4_C_4)  [4\_C\_4](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=4_C_4) | [1] Our Philosophy  1 minute  [2] Introduction  3 minutes  [3] Product Quality and Adverse Events  5 minutes  [4] Your Commitment  1 minutes  [5] Knowledge Check  5 minutes  Learning Progress  This Topic is now available. |  |
| [Screen 4](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=5_C_5)  [5\_C\_5](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=5_C_5) | We are a global, diverse healthcare company, and our customers depend on us to design and distribute safe products.  To do this, we must maintain a high level of integrity and vigilance in our processes and in the marketplace. It is our responsibility to understand what constitutes a product quality complaint and an adverse event, and how to report them internally. |  |
| [Screen 5](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=6_C_6)  [6\_C\_6](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=6_C_6) | It is important that the relevant quality or vigilance teams are informed as quickly as possible, so they can carefully assess whether Abbott has any obligation to file a report with regulatory authorities concerning an Abbott product quality complaint and/or adverse event. |  |
| [Screen 6](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=7_C_7)  [7\_C\_7](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=7_C_7) | All Abbott employees, no matter their roles and responsibilities, or the department they work for, must be diligent in reporting complaints – including product quality complaints and/or adverse events related to Abbott products – to the appropriate internal Abbott unit or function.  Not only is it the right thing to do to keep our customers safe; it is also the law. |  |
| [Screen 7](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=8_C_8)  [8\_C\_8](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=8_C_8) | For this course, Abbott products include pharmaceuticals, nutrition products, medical devices, diagnostics, and other products that are Abbott branded or branded with the name of any Abbott subsidiary, or for which Abbott is the exclusive distributor in any geography. |  |
| [Screen 8](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=9_C_9)  [9\_C\_9](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=9_C_9) | [1] Our Philosophy  1 minute  [2] Introduction  3 minutes  [3] Product Quality and Adverse Events  5 minutes  [4] Your Commitment  1 minutes  [5] Knowledge Check  5 minutes  Learning Progress  This Topic is now available. |  |
| [Screen 9](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=10_C_10)  [10\_C\_10](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=10_C_10) | What is a product complaint?  In this course, a product quality complaint is any written, electronic, or oral communication that alleges deficiencies in a distributed product related to:   * Physical characteristics * Identity * Quality * Purity * Potency * Durability * Reliability * Safety * Effectiveness * Performance   For infant formula only, any expression of dissatisfaction with the product is also considered a complaint. |  |
| [Screen 10](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=11_C_11)  [11\_C\_11](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=11_C_11) | What is an adverse event?  In this course, an adverse event is any untoward medical occurrence in a patient or clinical trial subject administered an Abbott product. An adverse event does not necessarily have a causal relationship with the product.  An adverse event can therefore be any unfavorable and/or unintended sign (e.g., abnormal laboratory finding), symptom, injury, or disease that happens close in time to the use of an Abbott product, whether or not it is related to the Abbott product. |  |
| [Screen 11](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=12_C_12)  [12\_C\_12](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=12_C_12) | Abbott employees are not only required, but also have the responsibility to report product quality complaints and adverse event information:   * To ensure patient safety, and the safety and efficacy of our products on the market. * To maintain compliance with local and international regulatory and legal reporting requirements, and Abbott policies and procedures. * To create areas of opportunity to further improve and develop Abbott products. * To give our customers confidence in our products and our processes. |  |
| [Screen 12](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=13_C_13)  [13\_C\_13](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=13_C_13) | Failure to comply with local and global reporting requirements has consequences.  It could increase product liability risk for Abbott. In the United States, it is an independent prohibited act in and of itself under the Federal Food, Drug, and Cosmetic Act.  More generally, it may constitute a breach of applicable product regulations, which is enforceable by the relevant national competent authority.  The product may be deemed misbranded. Introducing a misbranded device into interstate commerce is a prohibited act.  The commission of a prohibited act can lead to enforcement actions such as seizure, injunction, revocation of product licenses, criminal prosecution, and civil penalties. |  |
| [Screen 13](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=14_C_14)  Activity: Dialogue  [14\_C\_14](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=14_C_14) | Product quality complaint and adverse event information may come from various sources, in any format and at any time, including written, electronic, or oral communication or from social media. |  |
| [Screen 13](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=15_C_14)  [15\_C\_14](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=15_C_14) | Sources can include:   * Field service representatives * Scientific articles * Clinical trials * Sales and professional meetings * Friends * Family members * Vendors * Abbott Customer Hotlines |  |
| [Screen 14](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=16_C_16)  [16\_C\_16](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=16_C_16) | You may overhear a conversation in a physician’s office, or people may share customer complaints with you because they know you are an Abbott employee.  It is up to us to be aware and know what to do with this information. |  |
| [Screen 15](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=17_C_17)  [17\_C\_17](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=17_C_17) | As an Abbott employee, you are required to immediately report product quality complaints and adverse events internally (within 24 hours of awareness).  You must report the information internally even if you believe that a facility, healthcare professional, or anyone else will also report it. |  |
| [Screen 16](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=18_C_18)  [18\_C\_18](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=18_C_18) | If you are aware of a potential concern with an Abbott product, do not try to figure out if it is valid or not; report it immediately to the relevant Abbott quality or vigilance teams, or local representative.  They will assess whether Abbott has any obligation to file a report with the Food and Drug Administration (FDA) or with other regulatory authorities worldwide. |  |
| [Screen 17](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=19_C_19)  [19\_C\_19](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=19_C_19) | There are strict timelines set in various countries to file such reports from the moment of awareness.  It is important that the relevant quality or vigilance teams are informed as soon as possible. We want to do our best to identify potential risks and address them quickly. |  |
| [Screen 18](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=20_C_20)  [20\_C\_20](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=20_C_20) | A medical device reportable event includes:   * Any information that reasonably suggests that a marketed product has or may have caused or contributed to a serious injury or death. * If any product malfunctioned and the product or similar marketed product would be likely to cause or contribute to an injury or death if the malfunction were to recur.   Abbott product quality complaints must be reported to the relevant quality or vigilance teams to determine whether the complaint represents an event that is required to be reported to the FDA or to any other regulatory authorities. |  |
| [Screen 19](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=21_C_21)  [21\_C\_21](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=21_C_21) | Certain situations require reporting, even though no adverse event has occurred, to prevent adverse effects and to protect patient and public health. |  |
| [Screen 20](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=22_C_22)  [22\_C\_22](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=22_C_22) | For example, for pharmaceutical products, the following information needs to be reported immediately to Established Pharmaceuticals Division (EPD), Global Pharmacovigilance, or local representatives, even if no adverse event is associated with it:   * Transmammary exposure (transmission via breast milk) * Lack of efficacy (lack of effect) * Product exposure (maternal, paternal, or fetal) associated with pregnancy * Medication error * Overdose * Suspected transmission of an infectious agent * All exposure incurred by health professionals or non-professionals in the course of the product application to patients during their work * Off-label use (use beyond the approved label/package leaflet) * Inadvertent/accidental exposure * Abuse or misuse * Unexpected therapeutic or clinical benefit from use of the product |  |
| [Screen 21](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=23_C_23)  [23\_C\_23](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=23_C_23) | Where do you report product quality complaints or adverse event information?  Report product quality complaints and/or adverse event information you become aware of to your local applicable divisional quality organization or to a corporate quality representative. Each adverse event and safety-related situation needs to be immediately reported to your local division vigilance department in your organization. Visit Abbott World Quality and Regulatory for a list of divisional contacts to report a complaint or adverse event. Additional information is also available on the Vigilance Team Site.  Review the Resource page of this course for more information. |  |
| [Screen 22](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=24_C_24)  [24\_C\_24](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=24_C_24) | What information do you need to report?  At a minimum, do your best to collect the following information:  Who is reporting? Identifiable reporter and contact information for potential follow-up.  Who experienced the adverse event or the product quality complaint? Identifiable patient information (e.g., initials, gender, age, or age group).  What happened? Potential adverse event and/or product quality complaint.  What is the Abbott product? Product name (include any details like lot code, brand name, active ingredient, or any available product information). |  |
| [Screen 23](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=25_C_25)  [25\_C\_25](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=25_C_25) | When a potentially reportable adverse event is identified in a social media post, the minimum standard information that needs to be provided is the content of the entire post itself.  The relevant Abbott complaint handling group may need to follow up to gather additional information. Review the Resource page of this course for more information on Adverse Event/Social Media training. |  |
| [Screen 24](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=26_C_26)  [26\_C\_26](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=26_C_26) | Even if you do not have all the required information, report as much relevant information as possible.  Report it immediately and as soon as the adverse event or product quality complaint information and the product name are known. The patient and reporter identifiers may be collected later. The requirement is to report within 24 hours of awareness of the event.  Please observe Abbott’s privacy policies in each country. |  |
| [Screen 25](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=27_C_27)  [27\_C\_27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=27_C_27) | Quick Check  Test your knowledge now! |  |
| [Screen 25](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=28_C_27)  [28\_C\_27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=28_C_27) | Which of the statements below represent adverse event information that Abbott employees should report internally?  Select all that apply. |  |
| [Screen 25](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=29_C_27)  [29\_C\_27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=29_C_27) | An Abbott customer inquired about an Abbott product but has not experienced any deficiencies.  A suggestion by a neighbor to improve an Abbott pharmaceutical product, although he has not personally experienced problems with the medication.  A family member sharing an abnormal laboratory blood work finding after she consumed an Abbott product for several months.  Unfavorable symptoms reported by a clinical trial subject administered an Abbott pharmaceutical product.  Submit |  |
| [Screen 25](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=30_C_27)  [30\_C\_27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=30_C_27) | That's Correct!  That's Not Correct!  An adverse event is any unfavorable and/or unintended sign, symptom, injury, or disease that happens close in time to the use of an Abbott product, whether or not it is related to the Abbott product. An adverse event does not necessarily have a causal relationship with the product. |  |
| [Screen 26](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=31_C_28)  [31\_C\_28](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=31_C_28) |  |  |
| [Screen 26](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=32_C_28)  [32\_C\_28](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=32_C_28) | Which of the statements below represent adverse event information that Abbott employees should report internally? |  |
| [Screen 26](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=33_C_28)  [33\_C\_28](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=33_C_28) | Adverse event reporter’s contact information.  Brief summary of the adverse event that took place.  At least one patient identifier.  The Abbott product name.  All of the above  Submit |  |
| [Screen 26](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=34_C_28)  [34\_C\_28](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=34_C_28) | That's Correct!  That's Not Correct!  At a minimum, Abbott employees should do their best to report the following adverse event information:  Who is reporting?  Identifiable reporter and contact information for potential follow-up.  Who experienced the adverse event or the product quality complaint?  Identifiable patient information (e.g., initials, gender, age, or age group).  What happened?  Potential adverse event and/or product quality complaint.  What is the Abbott product?  Product name (include any details like lot code, brand name, active ingredient, or any available product information). |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=35_C_29)  [35\_C\_29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=35_C_29) | Click the arrow to begin your review.  Review  Take a moment to review some of the key concepts in this section. |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=36_C_29)  [36\_C\_29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=36_C_29) | Product Quality Complaint  A product quality complaint is any communication that alleges deficiencies in a distributed product related to physical characteristics, identity, quality, purity, potency, durability, reliability, safety, and/or effectiveness. |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=37_C_29)  [37\_C\_29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=37_C_29) | Adverse Event  An Adverse Event is any unexpected and inappropriate medical occurrence in a patient or clinical trial subject that happens close in time to the use of an Abbott product. |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=38_C_29)  [38\_C\_29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=38_C_29) | Source of Report  Product quality complaint and adverse event information may come from various sources, in any format and at any time, including written, electronic, or oral communication or from social media. |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=39_C_29)  [39\_C\_29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=39_C_29) | Timing of Report  You are required to immediately report product quality complaints and adverse events internally (within 24 hours of awareness) |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=40_C_29)  [40\_C\_29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=40_C_29) | Where to Report  Report all product quality complaints and/or adverse event information to your local applicable divisional quality organization or to a corporate quality representative. |  |
| [Screen 27](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=41_C_29)  [41\_C\_29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=41_C_29) | Adverse Event Information to Report  Always do your best to report the following adverse event information:   * Your name and contact information. * A summary of the potential adverse event * Identifiable patient information (e.g., initials, gender, age, or age group). * Abbott Product information Identifiable patient information (e.g., initials, gender, age, or age group). |  |
| [Screen 28](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=42_C_30)  [42\_C\_30](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=42_C_30) | [1] Our Philosophy  1 minute  [2] Introduction  3 minutes  [3] Product Quality and Adverse Events  5 minutes  [4] Your Commitment  1 minutes  [5] Knowledge Check  5 minutes  Learning Progress  This Topic is now available. |  |
| [Screen 29](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=43_C_30b)  [43\_C\_30b](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=43_C_30b) | At Abbott, our goal is to protect the safety, quality, and integrity of our products.  To accomplish this, we must always act in compliance with all global regulatory requirements and laws.  Abbott expects us to promptly report internally all product quality complaints and adverse events that involve or potentially involve Abbott products. We do this because it is the law, but also to protect the safety of our patients.  Use good judgment and ask for help whenever questions arise. |  |
| [Screen 30](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=44_C_31)  [44\_C\_31](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=44_C_31) | Take a moment to confirm your agreement with both statements.  I know what product quality complaints and adverse events are.  I understand the importance of quickly reporting product quality complaints and adverse events internally.  Confirm |  |
| [Screen 31](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=45_C_32)  [45\_C\_32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=45_C_32) | The Knowledge Check that follows consists of 5 questions. You must score 80% or higher to successfully complete this course.  WHEN YOU ARE READY, CLICK THE KNOWLEDGE CHECK BUTTON. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=46_C_33)  [46\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=46_C_33) | [1] Only scientists, DVPs, and salespeople are responsible for reporting internally an adverse event and product quality complaint. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=47_C_33)  [47\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=47_C_33) | [1] True  [2] False  Next |  |
| Screen 32  Question 1: Feedback  48\_C\_33 | All Abbott employees must be diligent about reporting adverse events or product quality complaints. Not only is it the right thing to do to keep our customers safe; it is also the law. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=49_C_33)  [49\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=49_C_33) | [2] Sources of potentially reportable events include social media outlets like Facebook, casual conversations at a backyard party, or even a professional trade journal. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=50_C_33)  [50\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=50_C_33) | [1] True  [2] False  Next |  |
| Screen 32  Question 2: Feedback  51\_C\_33 | Sources can include customer complaints, journal articles, clinical trials, sales/professional meetings, social media, friends, family members, and vendors. While this list is not exhaustive, you should be aware that potentially reportable events can exist in many different scenarios. It is up to us to be aware and know what to do. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=52_C_33)  [52\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=52_C_33) | [3] Reports can be submitted any time after an employee is aware of an issue. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=53_C_33)  [53\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=53_C_33) | [1] True  [2] False  Next |  |
| Screen 32  Question 3: Feedback  54\_C\_33 | As an Abbott employee, you are required to immediately report an adverse event, and product quality complaint, internally (within 24 hours of awareness). There are strict timelines set in various countries to file reports from the moment of awareness, therefore it is important that the relevant quality and vigilance teams are informed as quickly as possible. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=55_C_33)  [55\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=55_C_33) | [4] Dissatisfaction with an infant formula product should be reported as a complaint. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=56_C_33)  [56\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=56_C_33) | [1] True  [2] False  Next |  |
| Screen 32  Question 4: Feedback  57\_C\_33 | For infant formula only, any expression of dissatisfaction with the product will also be considered a complaint. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=58_C_33)  [58\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=58_C_33) | [5] You hear about a potential adverse event, but you believe it was already reported or will be reported by someone else anyway, or you do not believe there is an issue with our medical device. There is no need to report. |  |
| [Screen 32](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=59_C_33)  [59\_C\_33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=59_C_33) | [1] True  [2] False  Submit |  |
| Screen 32  Question 5: Feedback  60\_C\_33 | If you are aware of a concern with an Abbott product, report it immediately to the relevant quality and/or vigilance teams. Do not try to figure out if the concern is valid or not or if it has already been brought to the attention of the organization. |  |
| [Screen 33](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=61_C_34)  [61\_C\_34](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=61_C_34) | No results are available, as you have not completed the Knowledge Check.  Congratulations! You have successfully passed the Knowledge Check.  Please review your results below by clicking on each question.  Once you’re done, click the forward arrow to take a short survey.  Sorry, you did not pass the Knowledge Check. Take a few minutes to review your results below by clicking on each question.  When you are done, click the Retake button. |  |
| [Screen 34](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=62_C_35)  [62\_C\_35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=62_C_35) | This survey is optional.  Important: Whether you choose to complete the survey or not, you must click the EXIT (X) icon in the course title bar to complete the course and upload your results. |  |
| [Screen 34](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=63_C_35)  [63\_C\_35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=63_C_35) | [1] How would you rate this course overall?  Bad  Poor  Average  Great  Excellent |  |
| [Screen 34](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=64_C_35)  [64\_C\_35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=64_C_35) | [2] Please further explain your rating. |  |
| [Screen 34](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=65_C_35)  [65\_C\_35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=65_C_35) | [3] As a result of this session, I have a better understanding of Product Quality Complaint and Adverse Event Reporting at Abbott.  Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree |  |
| [Screen 34](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=66_C_35)  [66\_C\_35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=66_C_35) | [4] To what extent is the content covered in this course relevant to your work?  Not at All Relevant  Not Really Relevant  Undecided  Somewhat Relevant  Very Relevant |  |
| [Screen 34](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=67_C_35)  [67\_C\_35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=67_C_35) | [5] Which of the topics covered in this course would you like to learn more about?  Click the Upload button to complete the course, upload your data, and close the course window.  Upload |  |
| [Screen 35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=68_C_200)  [68\_C\_200](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=68_C_200) | Where to Go for Support |  |
| [Screen 35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=69_C_200)  [69\_C\_200](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=69_C_200) | MANAGER  If you have a question or need guidance about potential concerns involving product quality complaint or adverse event reporting, speak with your manager. |  |
| [Screen 35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=70_C_200)  [70\_C\_200](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=70_C_200) | Abbott QUALITY and REGULATORY  Visit [Abbott World Quality and Regulatory](https://abbott.sharepoint.com/sites/abbottworld/Quality/Pages/Home.aspx?icid=AW_MN_ORG_AQR) and navigate to:   * Quality Systems for more information on [Complaints and Product Actions (AQ04)](https://abbott.sharepoint.com/sites/AW-AQ04), [who to call to report a complaint or adverse event](https://abbott.sharepoint.com/sites/AW-AQ04/sitepages/WhodoIcalltoreportacomplaintoradverseevent.aspx), and the [Vigilance Team Site](https://abbott.sharepoint.com/sites/AW-AQ04/SitePages/Vigilance-Home-Page.aspx). * Policies for [Abbott Quality and Regulatory - Global Policy Portal](https://abbott.sharepoint.com/sites/AW-GlobalPolicy).   Visit [Abbott World Quality and Regulatory Knowledge Management](https://abbott.sharepoint.com/sites/AW-QRKnowledge) for additional training.  [AQC5000e Responsibility for Reporting Complaints](https://abbott.sharepoint.com/sites/AW-QRKnowledge/SitePages/AQC5000e-Responsibility-for-Reporting-Complaints.aspx?web=1)  Visit [Digital Knowledge Center](https://abbott.sharepoint.com/sites/dkc/ENGLISH/Pages/default.aspx) for additional [Adverse Event/Medical Device Reporting/Social Media Training](https://abbott.sharepoint.com/sites/dkc/ENGLISH/Pages/Toolkit/Social/SMTraining.aspx). |  |
| [Screen 35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=71_C_200)  [71\_C\_200](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=71_C_200) | OFFICE OF ETHICS AND COMPLIANCE (OEC)  The OEC is a corporate resource available to address your compliance questions or concerns. Visit the [Abbott World OEC website](https://abbott.sharepoint.com/sites/AW-Ethics_Compliance). |  |
| [Screen 35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=72_C_200)  [72\_C\_200](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=72_C_200) | Legal REGULATORY AND COMPLIANCE  If you have questions about laws and regulations regarding product quality complaints, adverse events, or medical device reporting, Legal Regulatory and Compliance, can assist you. Visit the Abbott World [Legal website](https://abbott.sharepoint.com/sites/AW-Abbott-Legal). |  |
| [Screen 35](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=73_C_200)  [73\_C\_200](http://www.learnex.co.uk/test/AbbottProductQuality/courses/EN-US/course/index.html?showScreen=73_C_200) | Course Resources  Transcript  Click [here](file:///C:\dev\AbbottProductQuality\courses\EN-US\translation\reference\Transcript.pdf) for a full transcript of the course |  |
| 74\_toc\_1 | Our Philosophy |  |
| 75\_toc\_2 | Product Quality Complaint and Adverse Event Reporting at Abbott |  |
| 76\_toc\_3 | Our Philosophy |  |
| 77\_toc\_4 | Objectives |  |
| 78\_toc\_5 | Table Of Contents |  |
| 79\_toc\_6 | Introduction |  |
| 80\_toc\_7 | Introduction |  |
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| 82\_toc\_9 | Product Quality and Adverse Events |  |
| 83\_toc\_10 | Defining Product Quality and Adverse Events |  |
| 84\_toc\_11 | Requirements and Responsibilities |  |
| 85\_toc\_12 | Reporting |  |
| 86\_toc\_13 | Quick Check |  |
| 87\_toc\_14 | Review |  |
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| 89\_toc\_16 | Your Commitment |  |
| 90\_toc\_17 | Your Commitment |  |
| 91\_toc\_18 | Knowledge Check |  |
| 92\_toc\_19 | Introduction |  |
| 93\_toc\_20 | Assessment |  |
| 94\_toc\_21 | Feedback |  |
| 95\_toc\_22 | Survey |  |
| 96\_string\_1 | The Course cannot contact the LMS. Click 'OK' to continue and review the course. Note, Course Certification may not be available. Click 'Cancel' to exit |  |
| 97\_string\_2 | All questions remain unanswered |  |
| 98\_string\_3 | Questions |  |
| 99\_string\_4 | Question |  |
| 100\_string\_5 | not answered |  |
| 101\_string\_6 | That's correct! |  |
| 102\_string\_7 | That's not correct! |  |
| 103\_string\_8 | Feedback: |  |
| 104\_string\_9 | Product Quality Complaint and Adverse Event Reporting at Abbott |  |
| 105\_string\_10 | Knowledge Check |  |
| 106\_string\_11 | Submit |  |
| 107\_string\_12 | Retake |  |
| 108\_string\_13 | Course Description: This course was designed to help clarify what is expected of Abbott employees when we become aware of Abbott product quality complaints and adverse events. This course should take about 20-25 minutes to complete. |  |
| 109\_string\_14 | Menu |  |
| 110\_string\_15 | Resources |  |
| 111\_string\_16 | Reference Material |  |
| 112\_string\_17 | Audio |  |
| 113\_string\_18 | Exit |  |
| 114\_string\_19 | Close |  |
| 115\_string\_20 | Comment... |  |