

fda medical device training requirements

FDA Medical Device Training Requirements: What You Need to Know

fda medical device training requirements are a critical component in ensuring that manufacturers, distributors, and users of medical devices comply with regulatory standards and maintain product safety and effectiveness. Whether you're involved in the design, production, or post-market surveillance of medical devices, understanding these training mandates is essential. This article delves into the key aspects of FDA medical device training requirements, how organizations can implement effective training programs, and why adherence is fundamental not only for compliance but also for patient safety.

Understanding FDA Medical Device Training Requirements

The U.S. Food and Drug Administration (FDA) regulates medical devices to ensure they meet safety and performance standards. One of the less-discussed but equally important aspects of FDA regulations is personnel training. The FDA expects that all individuals who handle medical devices in various capacities—from manufacturing to quality control—receive proper training tailored to their roles.

The Regulatory Foundation: 21 CFR Part 820

The cornerstone regulation governing medical device manufacturing and quality systems in the U.S. is 21 CFR Part 820, also known as the Quality System Regulation (QSR). Within the QSR framework, section 820.25 specifically addresses personnel training. It mandates that manufacturers establish and maintain procedures to ensure all employees are trained adequately to perform their assigned tasks.

This means training is not a one-time event but a continuous process that must be documented and updated as processes, technologies, or regulatory requirements evolve. The FDA expects companies to have written training procedures and evidence of training effectiveness – this often includes competency assessments and retraining when necessary.

Why Training is Critical Beyond Compliance

Beyond regulatory compliance, effective FDA medical device training requirements play a vital role in risk management. Well-trained staff reduce errors during manufacturing, inspection, and distribution processes, which directly impact product quality and patient safety. Moreover, training helps organizations stay agile and prepared during FDA inspections, audits, and product recalls.

Key Elements of an Effective Medical Device Training Program

Meeting FDA medical device training requirements involves more than checking off boxes. Creating a robust training program involves several key components that ensure both compliance and operational excellence.

1. Comprehensive Training Needs Analysis

The first step is identifying the training needs based on job functions and responsibilities. This includes understanding which employees require specific knowledge about device design controls, quality assurance processes, or regulatory documentation. Conducting a thorough training needs analysis helps tailor the program and prevents unnecessary or irrelevant training sessions.

2. Developing Detailed Training Procedures

FDA regulations require documented procedures for training. These procedures should outline:

- Objectives and scope of the training
- Roles and responsibilities for trainers and trainees
- Training delivery methods (e.g., in-person, e-learning, hands-on)
- Frequency of training and retraining
- Methods for evaluating training effectiveness
- Recordkeeping and documentation standards

Having clear procedures ensures consistency across the organization and creates a reference point during FDA inspections.

3. Delivering Role-Specific Training

Training must be relevant to the tasks employees perform. For example, personnel involved in device manufacturing must understand Good Manufacturing Practices (GMP), while those in quality control might require deeper insight into inspection techniques and defect analysis. Tailoring training content ensures employees gain applicable knowledge that enhances their job performance.

4. Ongoing Competency Assessment and Retraining

Simply attending a training session isn't enough. The FDA expects organizations to verify that employees have understood and can apply their training. This is typically done through testing, practical demonstrations, or supervisory evaluations. When gaps are identified, retraining is necessary to maintain compliance and quality standards.

5. Maintaining Training Records

Accurate and accessible training records are a regulatory requirement. These records should detail who was trained, when, the content covered, and evidence of competency. Keeping these records organized is vital during FDA inspections and internal audits.

Challenges in Meeting FDA Medical Device Training Requirements

While the requirements themselves are straightforward, many organizations face challenges in implementing effective training programs.

Keeping Up with Regulatory Changes

FDA regulations and guidance documents related to medical devices are periodically updated. Staying current with these changes and integrating them into training programs requires dedicated resources and continuous monitoring.

Training Across Multiple Locations

For companies with operations spread across different regions or countries, ensuring consistent training quality and documentation can be complex. Variations in language, culture, and local regulations add layers of difficulty.

Balancing Training Frequency and Operational Demands

Frequent training and retraining are necessary, but they must be balanced against production schedules and workflow. Too much training can disrupt operations, while too little risks non-compliance.

Tips for Implementing an FDA-Compliant Medical Device Training Program

Creating a training program that meets FDA medical device training requirements doesn't have to be overwhelming. Here are some practical tips:

- **Leverage Technology:** Use Learning Management Systems (LMS) to automate training schedules, track progress, and store records securely.
- **Engage Subject Matter Experts:** Incorporate experts from various departments to develop relevant and up-to-date training content.
- **Incorporate Real-World Scenarios:** Use case studies or simulations to help employees connect training material with real tasks.
- **Encourage Feedback:** Regularly solicit trainee feedback to improve the training process and materials.
- **Regularly Review and Update Training Materials:** Ensure content reflects current regulations, standards, and company processes.

The Role of FDA Inspections in Training Compliance

FDA inspections often include a review of training records and interviews with personnel to assess whether staff are adequately trained. Inspectors look for documented procedures, evidence of training completion, and proof

that employees understand their roles related to quality systems.

Non-compliance with training requirements can lead to Form 483 observations, warning letters, or even product recalls. Therefore, proactive management of training programs is crucial to minimize regulatory risks.

Integrating Training with Quality Management Systems

Many medical device companies align their training programs with their overall Quality Management System (QMS). Standards such as ISO 13485 specify requirements for training and competence, complementing FDA mandates.

Integrating training into the QMS facilitates a more holistic approach to quality, where employee competence, process controls, and corrective actions work together to ensure device safety and compliance.

Conclusion: Embracing Training as a Strategic Asset

FDA medical device training requirements are more than regulatory hurdles—they represent an opportunity for organizations to strengthen their processes, empower employees, and safeguard patients. By adopting a thoughtful, comprehensive training approach, medical device companies not only comply with FDA standards but also build a culture of quality and continuous improvement that drives long-term success.

Frequently Asked Questions

What are the FDA requirements for medical device training?

The FDA requires that medical device manufacturers provide appropriate training to ensure that employees are competent in their roles related to device design, production, and quality control. Training must be documented and updated as necessary to comply with Quality System Regulation (QSR) under 21 CFR Part 820.

Is training mandatory for medical device

manufacturing under FDA regulations?

Yes, training is mandatory under the FDA's Quality System Regulation (21 CFR Part 820.25). Manufacturers must establish and maintain procedures for identifying training needs and ensuring personnel are trained adequately to perform their assigned responsibilities.

What topics should FDA medical device training cover?

Training should cover device-specific manufacturing processes, quality control procedures, regulatory requirements, product safety, and documentation practices. It should also include updates on any changes to processes, standards, or regulations.

How often does FDA medical device training need to be conducted?

Training should be provided when employees are hired, when job responsibilities change, or when new processes or regulations are introduced. Refresher training should be conducted periodically to maintain compliance and competency.

Does the FDA require documentation of medical device training?

Yes, the FDA requires documentation of all training activities, including the content, attendees, dates, and effectiveness assessments. This documentation is essential for compliance audits and inspections.

Are there specific qualifications for trainers in FDA medical device training?

While the FDA does not specify qualifications for trainers, they must be qualified by education, training, or experience to conduct effective training sessions relevant to medical device manufacturing and regulatory requirements.

How does FDA medical device training relate to corrective and preventive actions (CAPA)?

Training is a critical component of CAPA. When issues are identified, training may be required to address root causes, prevent recurrence, and ensure compliance with FDA regulations.

What role does FDA medical device training play in regulatory inspections?

During FDA inspections, training records are reviewed to ensure compliance with 21 CFR Part 820. Inspectors assess whether employees are adequately trained and whether training programs are effective and documented.

Can online training fulfill FDA medical device training requirements?

Yes, online training can fulfill FDA requirements if it effectively covers the necessary content, ensures participant understanding, and is properly documented. The training method must demonstrate competency and compliance.

Additional Resources

FDA Medical Device Training Requirements: Navigating Compliance and Quality Assurance

fda medical device training requirements represent a critical component of regulatory compliance and quality management in the medical device industry. As the Food and Drug Administration (FDA) enforces stringent regulations to ensure patient safety and product efficacy, organizations involved in the design, manufacture, and distribution of medical devices must adhere to specific training protocols. These requirements not only support operational excellence but also mitigate risks associated with device failures and regulatory penalties.

Understanding the scope and nuances of FDA medical device training requirements is essential for manufacturers, quality assurance professionals, and regulatory affairs specialists. The complexity of the guidelines, coupled with evolving technological advancements, demands a thorough grasp of regulatory expectations and best practices for workforce education.

Overview of FDA Medical Device Training Requirements

The FDA's approach to medical device training is embedded within its quality system regulations (QSR), primarily outlined in 21 CFR Part 820. This regulation mandates a comprehensive quality management system (QMS) that includes personnel training as a foundational element. The objective is to ensure that employees possess the necessary skills and knowledge to perform their assigned responsibilities effectively.

Under 21 CFR 820.25, personnel must be adequately trained and their training documented. This section emphasizes that personnel should be competent based

on appropriate education, training, and experience. The regulation requires organizations to establish training procedures, including identification of training needs, provision of training, and evaluation of effectiveness.

Key Regulatory Expectations

The FDA does not prescribe a rigid training curriculum but expects manufacturers to develop training programs tailored to their specific processes and device types. Key expectations include:

- **Training Needs Analysis:** Identifying roles and associated skill gaps aligned with regulatory and operational requirements.
- **Documented Training Procedures:** Establishment of formal procedures describing how training is delivered, recorded, and assessed.
- **Training Effectiveness Evaluation:** Ensuring that training achieves its intended outcomes through assessments, audits, or performance metrics.
- **Continuous Education:** Ongoing training to keep pace with regulatory updates, technological changes, and quality system improvements.

Components of Effective FDA Medical Device Training Programs

Developing an effective training program that complies with FDA requirements involves several critical components. These components help organizations maintain control over their quality systems while fostering a culture of safety and compliance.

1. Customized Training Content

Training content must be device-specific and role-specific. For example, employees working in design and development require detailed knowledge of design controls, risk management, and documentation standards. Conversely, manufacturing personnel need to be proficient in process controls, equipment operation, and quality inspection methods. Customization enhances relevance and ensures employees can apply their knowledge practically.

2. Comprehensive Documentation

Robust documentation is a cornerstone of FDA compliance. Training records should include:

- Training dates and attendance
- Curriculum or materials used
- Assessment results or certifications
- Records of refresher or additional training

This documentation provides traceability and evidentiary support during FDA inspections or audits.

3. Incorporation of Risk-Based Training

Risk management, as outlined in ISO 14971, complements FDA regulations and should inform training priorities. Employees involved in high-risk processes or critical device components warrant enhanced training focus. Incorporating a risk-based approach ensures that training resources are allocated efficiently and potential hazards are minimized.

4. Use of Technology and E-Learning

Modern training programs leverage technology to improve accessibility and tracking. E-learning platforms, webinars, and virtual simulations facilitate consistent training delivery across multiple sites and reduce logistical challenges. Additionally, digital tools can automate record-keeping and compliance monitoring, thereby reducing administrative burdens.

Challenges and Considerations in Meeting FDA Training Requirements

While FDA medical device training requirements provide a regulatory framework, implementing effective training programs can be complex. Several challenges often arise:

Balancing Compliance and Practicality

Manufacturers must balance regulatory rigor with operational efficiency. Overly burdensome training programs may lead to employee disengagement, whereas inadequate training risks non-compliance and product issues. Finding the optimal balance requires continuous feedback and refinement.

Keeping Pace with Regulatory Changes

The medical device regulatory landscape is dynamic. Amendments to FDA guidance documents, harmonization with international standards, and technological innovations necessitate ongoing updates to training content. Organizations must establish mechanisms to monitor changes and promptly integrate them into training curricula.

Cross-Functional Training Needs

Medical device development and manufacturing involve multiple departments, including research and development, quality assurance, manufacturing, and regulatory affairs. Each function has distinct training needs, making it essential to coordinate training efforts to avoid redundancy and ensure comprehensive coverage.

Ensuring Training Effectiveness

Simply delivering training is insufficient. Measuring its effectiveness through assessments, on-the-job performance evaluations, and audits is vital. The FDA expects evidence that training has successfully enhanced employee competence and supported quality outcomes.

Comparative Insights: FDA Training Requirements vs. International Standards

Globally, medical device manufacturers often navigate multiple regulatory frameworks. The FDA's training requirements align closely with international standards such as ISO 13485, which also emphasizes personnel competence and training as part of the QMS.

ISO 13485 mandates documented procedures for training and competence evaluation, paralleling FDA expectations. However, ISO 13485 extends to include training related to risk management and regulatory compliance more explicitly, offering a broader perspective. Companies operating in global

markets benefit from integrating FDA requirements with ISO standards to create unified training programs that satisfy multiple regulatory bodies.

Best Practices for Sustained Compliance and Quality

Organizations aiming to excel in FDA medical device training requirements can adopt best practices that enhance both compliance and operational quality:

1. **Conduct Regular Training Audits:** Internal audits help identify gaps and opportunities for improvement in training programs.
2. **Engage Leadership Support:** Management commitment ensures adequate resources and fosters a culture valuing continuous learning.
3. **Implement Competency Matrices:** Mapping roles against required skills and training ensures targeted and efficient workforce development.
4. **Leverage Feedback Mechanisms:** Soliciting employee input on training effectiveness can guide enhancements and increase engagement.
5. **Integrate Training with Quality Metrics:** Linking training outcomes to quality indicators helps demonstrate training impact on product safety and compliance.

By embedding these strategies, manufacturers can transform regulatory obligations into competitive advantages.

As the medical device industry evolves, FDA medical device training requirements serve as a pivotal factor in safeguarding patient health and ensuring product integrity. Staying ahead with well-structured, documented, and effective training not only aligns with regulatory mandates but also enhances organizational resilience and market reputation.

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fda medical device training requirements: Medical device reporting improvements needed in FDA's system for monitoring problems with approved devices : report to congressional committees ,

fda medical device training requirements: Medical Device Reporting United States. General Accounting Office, 1997

fda medical device training requirements: *The Biomedical Quality Auditor Handbook, Third Edition* Heather Crawford, 2017-09-08 The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the biomedical community. This third edition correlates to the 2013 exam Body of Knowledge (BoK) and reference list for ASQ's Certified Biomedical Auditor program. It includes updates and corrections to errors and omissions in the second edition. Most notably it has been re-organized to align more closely with the BoK.

fda medical device training requirements: Medical Devices Bulletin ,

fda medical device training requirements: Writing In-House Medical Device Software in Compliance with EU, UK, and US Regulations Philip S. Cosgriff, Matthew J. Memmott, 2024-03-26 This book is a comprehensive guide to producing medical software for routine clinical use. It is a practical guidebook for medical professionals developing software to ensure compliance with medical device regulations for software products intended to be sold commercially, shared with healthcare colleagues in other hospitals, or simply used in-house. It compares requirements and latest regulations in different global territories, including the most recent EU regulations as well as UK and US regulations. This book is a valuable resource for practising clinical scientists producing medical software in-house, in addition to other medical staff writing small apps for clinical use, clinical scientist trainees, and software engineers considering a move into healthcare. The academic level is post-graduate, as readers will require a basic knowledge of software engineering principles and practice. Key Features: Up to date with the latest regulations in the UK, the EU, and the US Useful for those producing medical software for routine clinical use Contains best practice

fda medical device training requirements: Healthcare Hazard Control and Safety Management James T. Tweedy, 1996-12-09 Healthcare Hazard Control and Safety Management presents the most comprehensive and up-to-date coverage ever published for any healthcare professional serving in safety, occupational health, hazard materials management, quality improvement, and risk management positions. No area of healthcare safety is ignored in this major work. Here is a single-volume reference that is convenient to use, written in an easy-to-read and understandable format. In addition to providing easily digested information, the author has constructed practical checklists and forms that can be readily put to use. It is a fact that there is a real need for professionals who understand and can assist in controlling the numerous and serious hazards found in healthcare facilities and resulting from activities within those facilities. Today's hospital and healthcare administrator is looking for the most capable individuals to fill positions that require skills in hazard control. The material in Healthcare Hazard Control and Safety Management provides this much-needed information and addresses the requirements of the Board of Certified Healthcare Safety Management. Important topics covered include: safety management, workers' compensation, risk control, quality improvement, and stress management. Strong emphasis is placed on accident investigation, hazard identification, and safety training. If you are looking for a single volume that covers the areas of life safety, fire prevention, emergency management, biohazards, waste management, healthcare ergonomics, maintenance and engineering hazards, security, radiation and lab safety issues, nursing services and patient care, pharmacy support, food services and sanitation, or environmental services...this book is for you!

fda medical device training requirements: Managing Medical Devices within a Regulatory Framework Beth Ann Fiedler, 2016-09-10 Managing Medical Devices within a Regulatory Framework helps administrators, designers, manufacturers, clinical engineers, and

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fda medical device training requirements: *Medical Regulatory Affairs* Jack Wong, Raymond K. Y. Tong, 2022-01-27 This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Experts from influential international regulatory bodies, including the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency, Japan Pharmaceuticals and Medical Devices Agency, Saudi Food and Drug Authority, Korea Testing Laboratory, Taiwan FDA, World Health Organization, Asian Harmonization Working Party, Regulatory Affairs Professionals Society, and British Standards Institution, have contributed to the book. Government bodies, the medical device industry, academics, students, and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects.

fda medical device training requirements: *Trends in Development of Medical Devices* Prakash Srinivasan Timiri Shanmugam, Logesh Chokkalingam, Pramila Bakthavachalam, 2020-01-25 Trends in Development of Medical Devices covers the basics of medical devices and their development, regulations and toxicological effects, risk assessment and mitigation. It also discusses the maintenance of a medical device portfolio during product lifecycle. This book provides up-to-date information and knowledge on how to understand the position and benefits of new introduced medical devices for improving healthcare. Researchers and industry professionals from the fields of medical devices, surgery, medical toxicology, pharmacy and medical devices manufacture will find this book useful. The book's editors and contributors form a global, interdisciplinary base of knowledge which they bring to this book. - Provides a roadmap to medical devices development and the integration of manufacturing steps to improve workflows - Helps engineers in medical devices industries to anticipate the special requirements of this field with relation to biocompatibility, sterilization methods, government regulations - Presents new strategies that readers can use to take advantage of rapid prototyping technologies, such as 3D printing, to reduce imperfections in production and develop products that enable completely new treatment possibilities

fda medical device training requirements: *Medical Device Design and Regulation* Carl T. DeMarco, 2011-01-24 The intent of this book (MDDR, for short) is to present an introduction to, and overview of, the world of medical device regulation by the United States Food and Drug Administration (FDA), and the relationship of this regulatory scheme to the design and development of medical devices. In providing this information, the book covers the broad range of requirements, which are presented within eight major topics: background and regulatory environment, device

design control, nonclinical testing, clinical testing, marketing applications, post-market requirements, quality systems/GMPs, and compliance/enforcement. This book provides students and professionals in the medical device industry with a road map to the regulation of medical devices. It provides a broad understanding of the breadth and depth of medical device regulation by collecting in one textbook coverage of the regulatory scheme for medical devices in terms that are suitable for engineers, scientists, and healthcare providers. The vast amount of information available on the subject is distilled into a concise and coherent presentation. There also are problems and projects at the end of each chapter. In addition to the usual questions requiring specific answers, the projects include the drafting of a device control plan, the development of a nonclinical test procedure, the resolution of a recall, the response to a Warning Letter, and the creation of a CAPA for a device deficiency. A solutions manual for these exercises is available to teachers who adopt the textbook for classroom use or for employee training. Medical Device Design and Regulation (MDDR) also makes available over 100 complimentary live hyperlinks to web pages with additional relevant information, and offers users the opportunity to join and participate in the "MDDR Users Group" on LinkedIn.

fda medical device training requirements: *Departments of Labor and Health, Education, and Welfare and Related Agencies Appropriations for Fiscal Year 1978* United States. Congress. Senate. Committee on Appropriations. Subcommittee on Departments of Labor, and Health, Education, and Welfare, and Related Agencies, 1977

fda medical device training requirements: *FDA's Foreign Drug Inspection Program* United States. Congress. House. Committee on Energy and Commerce. Subcommittee on Oversight and Investigations, 2008

fda medical device training requirements: *Reprocessing of Single-use Medical Devices* United States. Congress. Senate. Committee on Health, Education, Labor, and Pensions, 2000

fda medical device training requirements: *Federal Register* , 2013-11

fda medical device training requirements: *The Medical Device Industry* Norman F. Estrin, 1990-08-31 Practical information about the complexities of biomedical technology and regulation, and their implications for manufacturers and marketers of health care devices. Written primarily for those in the industry concerned about staying competitive in light of complex and fluctuating regulatory approach

fda medical device training requirements: *Cognitive Aging* Institute of Medicine, Board on Health Sciences Policy, Committee on the Public Health Dimensions of Cognitive Aging, 2015-07-21 For most Americans, staying mentally sharp as they age is a very high priority. Declines in memory and decision-making abilities may trigger fears of Alzheimer's disease or other neurodegenerative diseases. However, cognitive aging is a natural process that can have both positive and negative effects on cognitive function in older adults - effects that vary widely among individuals. At this point in time, when the older population is rapidly growing in the United States and across the globe, it is important to examine what is known about cognitive aging and to identify and promote actions that individuals, organizations, communities, and society can take to help older adults maintain and improve their cognitive health. Cognitive Aging assesses the public health dimensions of cognitive aging with an emphasis on definitions and terminology, epidemiology and surveillance, prevention and intervention, education of health professionals, and public awareness and education. This report makes specific recommendations for individuals to reduce the risks of cognitive decline with aging. Aging is inevitable, but there are actions that can be taken by individuals, families, communities, and society that may help to prevent or ameliorate the impact of aging on the brain, understand more about its impact, and help older adults live more fully and independent lives. Cognitive aging is not just an individual or a family or a health care system challenge. It is an issue that affects the fabric of society and requires actions by many and varied stakeholders. Cognitive Aging offers clear steps that individuals, families, communities, health care providers and systems, financial organizations, community groups, public health agencies, and others can take to promote cognitive health and to help older adults live fuller and more independent lives. Ultimately, this report calls for a societal commitment to cognitive aging as a public health issue that requires prompt action across many

sectors.

fda medical device training requirements: Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad Institute of Medicine, Board on Health Sciences Policy, Board on Global Health, Committee on Strengthening Core Elements of Food and Drug Regulatory Systems in Developing Countries, 2012-09-03 A very high portion of the seafood we eat comes from abroad, mainly from China and Southeast Asia, and most of the active ingredients in medicines we take originate in other countries. Many low- and middle-income countries have lower labor costs and fewer and less stringent environmental regulations than the United States, making them attractive places to produce food and chemical ingredients for export. Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad explains that the diversity and scale of imports makes it impractical for U.S. Food and Drug Administration (FDA) border inspections to be sufficient to ensure product purity and safety, and incidents such as American deaths due to adulterated heparin imported from China propelled the problem into public awareness. The Institute of Medicine Committee on Strengthening Core Elements of Regulatory Systems in Developing Countries took up the vital task of helping the FDA to cope with the reality that so much of the food, drugs, biologics, and medical products consumed in the United States originate in countries with less-robust regulatory systems. Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad describes the ways the United States can help strengthen regulatory systems in low and middle income countries and promote cross-border partnerships - including government, industry, and academia - to foster regulatory science and build a core of regulatory professionals. This report also emphasizes an array of practical approaches to ensure sound regulatory practices in today's interconnected world.

fda medical device training requirements: 107-1 Hearings: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2002, Part 4, March 8, 2001, 2001

fda medical device training requirements: Discussion Draft of the Food and Drug Administration Globalization Act Legislation: Device and Cosmetic Safety Provisions, Serial No. 110-117, May 14, 2008, 110-2 Hearing, *, 2010

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