Supplementary file 4

Filled in RA&RC templates after the final assessment of the nine participating hospital pharmacies

	Supplemental material	placed on this supplemental materi	ai wii	cii nas	Deen	supplied	by the author(s)
macy 1	risk assessment	t after initial audit					
rces of risk	risk reduction	remaining risk after first audit	S	0	D	R P N 1	additional risk reduction
	SC checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air sampling by settle plate	1. chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10	no
		 materials and equipment disturb the unidirectional airflow and can block first air at critical spots 	5	2	3	30	correct position of materials after inver- visualization in worst case situation; pregularly audited; both operators corr
SC	disinfection before each work session by wiping with ethanol 70% impregnated wipes; daily monitoring by contact plate; disinfection at the beginning of a working day is registered in a log	1. contamination by materials used during preparation	5	3	2	30	disinfection before each new prepare disinfection before each new prepare regularly audited
ceiling SC	daily surface disinfection by wiping with ethanol 70% impregnated wipes; disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	5	no
with a sterile	unwrapping in front of SC; all operators in	1. contaminated outer layer	5	2	2	20	original boxes are unpacked in front o

Hospital pharmacy 1 risk assessment after initial audit results after final asses								results after final	assessment				
	sources of risk	risk reduction	remaining risk after first audit	S (o I	D	R P N 1	additional risk reduction	remaining risk	s	0	D	R P N 2
A	Air	SC checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air sampling by settle plate	1. chance of environment around work zone at rest not in accordance with Grade A air	5	1 :	2	10	no	chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10
			2. materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5	2 :	3	30	correct position of materials after investigation by airflow visualization in worst case situation; position of materials is regularly audited; both operators correct each other	unlikely	5	1	1	5
В	Worktop SC	disinfection before each work session by wiping with ethanol 70% impregnated wipes; daily monitoring by contact plate; disinfection at the beginning of a working day is registered in a log	1. contamination by materials used during preparation	5	3 2	2	30	disinfection before each new prepared dosage form; disinfection before each new prepared dosage form is regularly audited	unlikely	5	1	1	5
C	Wall and ceiling SC	daily surface disinfection by wiping with ethanol 70% impregnated wipes; disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	5	no	unlikely	5	1	1	5
D1	Materials with a sterile surface (sterile devices	unwrapping in front of SC; all operators in background area wear disposable gloves; materials	1. contaminated outer layer	5	2 2	2	20	original boxes are unpacked in front of lock with gloved hands	transfer and storage is not audited	5	1	2	10
	and infusion bags)	are used directly and/or store in closed cupboards	2. parts of outer layer inside SC	5	3 2	2	30	aseptic transfer is regularly audited and both operators correct each other	no aseptic transfer into SC by presentation	5	2	1	10
D2	Critical spots (syringe tips, needles and the opening of tubes)*		1. contact of critical spots with the work top of SC	5	4 :	3	60	putting down syringes, needles and open tubes on a sterile pad in SC; use of sterile pad is regularly audited; both operators correct each other	unlikely	5	1	1	5
E1	Materials and equipment with a non- sterile surface	disinfection by wiping with ethanol 70% impregnated wipes	1. high surface bioburden before disinfection	5	3 :	3	45	ampoules and vials are transferred into the anteroom in their original boxes; materials are used directly and/or stored in closed cupboards	no periodical surface bioburden determination before disinfection; transfer and storage is not audited	5	1	3	15
	(ampoules, vials, bottles)		2. disinfection improperly done	5	4 4	4	80	thorough wiping by completely impregnated wipes; disinfection is regularly audited and both operators correct each other	no validated disinfection procedure; no regular surface monitoring of disinfected materials	5	2	3	30
			3. recontamination of disinfected materials	5	4 :	2	40	measures to prevent recontamination; measures to prevent changing disinfected and non-disinfected materials; measures are regularly audited and both operators correct each other	unlikely	5	1	1	5
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection in SC by wiping with sterile ethanol 70%	1. additional disinfection improperly done	5	3 4	4	60	precisely described and improved additinal disinfection technique; additional disinfection is regularly audited; both operators correct each other	still no assurance of a sterile surface	5	1	2	10
F	Operator's hands	sterile gloves, which are changed at least every hour; daily glove print by settle plate	1. glove damage	5	3 :	3	45	gloves integrity is tested immediately after putting them on and during processing; glove handling is regularly audited; both operators correct each other	unlikely	5	1	1	5
			2. surface contamination during putting on gloves	5	3 3	3	45	good putting on technique; putting on gloves is regularly audited; both operators correct each other	unlikely	5	1	1	5
			3. surface contamination during preparation	5	4 2	2	40	glove disinfection before start of each new preparation and every 15 min during a long preparation; glove disinfection is regularly audited and both operators correct each other	unlikely	5	1	1	5
G	Operator's forearm	wearing cleanroom clothing which is changed every day	1. surface contamination of the worktop	5	3 2	2	30	no	surface contamination of the worktop	5	3	2	30
Н	Working procedure	working with two operators during processing; SOPs; operators trained in aseptic techniques by broth simulations every year; process validation by broth simulation	 deviation from SOPs touching critical spots 	5	3 :	3 4	45 80	no additional training in non-touch working; non-touch working is regularly audited; both operators correct each other	deviation from SOPs chance of touch still exists	5 5	3 2	3 2	45 20
			3. SC (downflow), blocking first air at critical spots	5	3 :	3	45	prevention of blocking first air is regularly audited; both operators correct each other	chance of blocking first air still exists	5	2	1	10

HP 1, Hospital pharmacy 1; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 740, cumulative RPN after the initial audit; 230, cumulative RPN after the final assessment.

Hosp	ital pharmacy 2	risk assess	ment after initial audit					resul	ts after final assessment				
	sources of risk	risk reduction	remaining risk after first audit	s	0	D	R P N 1	additional risk reduction	remaining risk	s	0	D	R P N 2
A	Air	SC checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air	1. chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10	no	chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10
		sampling by settle plate	 materials and equipment disturb the unidirectional airflow and can block first air at critical spots 	5	2	3	30	no	materials and equipment disturb the unidirectional airflow which can result in blocking first air at critical spots	5	2	3	30
В	Worktop SC	disinfection before each work session by wiping with ethanol 70% impregnated wipes; daily monitoring by contact plate	1. disinfection forgotten; contamination by materials used during preparation	5	3	3	45	disinfection at the beginning of a working day is registered in a log	contamination by materials used during preparation still exists	5	3	2	30
С	Wall and ceiling SC	daily surface disinfection by wiping with ethanol 70% impregnated wipes	1. disinfection forgotten	5	1	2	10	disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	5
D1	Materials with a sterile surface (sterile devices and infusion	unwrapping in front of SC; materials are used directly and/or stored in closed cupboards	1. contaminated outer layer	5	3	2	30	all operators in background area wear disposable gloves	no unpacking original boxes in front of lock with gloved hands; transfer and storage is not audited	5	2	2	20
	bags)		2. parts of outer layer inside SC	5	3	2	30	no	parts of outer layer inside SC	5	2	3	30
D2	Critical spots (syringe tips, needles and the opening of tubes)		1. contact of critical spots with the work top of SC	5	4	3	60	no	contact of critical spots with the work top of SC	5	4	3	60
E1	Materials and equipment with a non-	disinfection by wiping with ethanol 70% impregnated wipes	1. high surface bioburden before disinfection	5	3	3	45	no	high surface bioburden before disinfection	5	3	3	45
	sterile surface		2. disinfection improperly done	5	4	4	80	no	disinfection improperly done	5	4	4	80
	(ampoules, vials, bottles)		3. recontamination of disinfected materials	5	4	2	40	no	recontamination of disinfected materials	5	4	2	40
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection in SC by wiping with sterile ethanol 70%	1. additional disinfection improperly done	5	3	4	60	no	additional disinfection improperly done	5	3	4	60
F	Operator's hands	wearing sterile gloves, which are changed	1. glove damage	5	2	3	30	no	glove damage	5	2	3	30
		at least every hour; good putting on	2. putting on gloves is not audited	5	2	3	30	no	putting on gloves is not audited	5	2	3	30
		technique; daily glove print by settle plate	3. surface contamination during preparation	5	4	2	40	glove disinfection before start of each new preparation and in between every 30 min	no glove disinfection every 15 min during a long preparation; glove disinfection is not regularly audited and both operators don't correct each other	5	3	2	30
G	Operator's forearm	wearing cleanroom clothing which is changed every day	1. surface contamination of the worktop	5	2	3	30	no	surface contamination of the worktop	5	2	3	30
Н	Working procedure	working with two operators during	1. deviation from SOPs	5	3	3	45	no	deviation from SOPs	5	3	3	45
		processing; SOPs; operators trained in	2. touching critical spots	5	4	4	80	no	touching critical spots	5	4	4	80
		aseptic techniques; aseptic process simulation with a broth solution	c. SC (downflow), blocking first air at critical spots	5	3	3	45	no	blocking first air at critical spots	5	3	3	45
	•		•	•	-		740		-		-	-	700

HP 2, Hospital pharmacy 2; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 740, cumulative RPN after the initial audit; 700, cumulative RPN after the final assessment.

uppl	lemental	materia	l

Hosp	ital pharmacy 3	risk asse	ssment after initial audit					results aft	er final assessment					
	sources of risk	risk reduction	remaining risk after first audit	S	0	D	R P 1 N	additional risk reduction	remaining risk	s	0	D	R P N	2
A	Air	SC checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air	1. chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10	no	chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10	0
		sampling by settle plate	2. materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5	2	3	30	no	materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5	2	3	30	0
В	Worktop SC	disinfection before each work session by wiping with ethanol 70% impregnated wipes; daily monitoring by contact plate	1. disinfection forgotten; contamination by materials used during preparation	5	3	3	45	disinfection at the beginning of a working day is registered in a log	contamination by materials used during preparation still excists	5	3	2	30	0
С	Wall and ceiling SC	daily surface disinfection by wiping with ethanol 70% impregnated wipes	1. disinfection forgotten	5	1	2	10	disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	5	5
D1	Materials with a sterile surface (sterile devices and infusion bags)	unwrapping in front of SC	1. contaminated outer layer	5	4	2	40	all operators in background area wear disposable gloves; original boxes are unpacked in front of lock with gloved hands; materials are used directly and/or stored in closed cupboards	transfer and storage is not audited	5	1	2	10	0
			2. parts of outer layer inside SC	5	3	2	30	aseptic transfer is regularly audited and both operators correct each other	no aseptic transfer into SC by presentation	5	2	1	10	0
D2	Critical spots (syringe tips, needles and the opening of tubes)		1. contact of critical spots with the work top of SC	5	4	3	60	putting down syringes, needles and open tubes on a sterile pad in SC; use of sterile pad is regularly audited; both operators correct each other	unlikely	5	1	1	5	5
E1	Materials and equipment with a non- sterile surface	disinfection by wiping with ethanol 70% impregnated wipes	1. high surface bioburden before disinfection	5	3	3	45	ampoules and vials are transferred in their original boxes into the background area; materials are used directly and/or stored in closed cupboards	no periodical surface bioburden determination before disinfection; transfer and storage is not audited	5	1	3	15	5
	(ampoules, vials, bottles)		2. disinfection improperly done	5	4	4	80	thorough wiping by completely impregnated wipes; disinfection is regularly audited and both operators correct each other	no validated disinfection procedure; no regular surface monitoring of disinfected materials	5	2	3	30	0
			 recontamination of disinfected materials 	5	4	2	40	measures to prevent recontamination; measures to prevent changing disinfected and non-disinfected materials; measures are regularly audited and both operators correct each other	unlikely	5	1	1	5	Ş
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection in SC by wiping with sterile ethanol 70%	1. additional disinfection improperly done	5	3	4	60	precisely described and improved additinal disinfection technique; additional disinfection is regularly audited; both operators correct each other	still no assurance of a sterile surface	5	1	2	10	0
F	Operator's hands	sterile gloves, which are changed at least every hour; daily glove print by settle plate	1. glove damage	5	3	3	45	gloves integrity is tested immediately after putting them on and during processing; glove handling is regularly audited; both operators correct each other	unlikely	5	1	1	5	5
			2. surface contamination during putting on gloves	5	3	3	45	no	surface contamination during putting on gloves	5	3	3	45	5
			3. surface contamination during preparation	5	4	2	40	no	surface contamination during preparation	5	4	2	4(0
G	Operator's forearm	wearing cleanroom clothing which is changed every day	1. surface contamination of the worktop	5	3	2	30	operator wears sterile sleeves which are changed after every session	unlikely	5	1	1	5	5
Н	Working procedure	working with two operators during processing; SOPs; operators trained in aseptic techniques; aseptic process	1. deviation from SOPs	5	3	3	45	accurate and up to date SOPs (enough details, univocal text); working according to SOPs is regularly audited; both operators correct each other	unlikely	5	1	1	5	5
		simulation with a broth solution	2. touching critical spots	5	4	4	80	additional training in non-touch working; non-touch working is regularly audited; both operators correct each other	chance of touch still excists	5	2	2	20	0
			3. SC (downflow), blocking first air at critical spots	5	3	3	45	prevention of blocking first air is regularly audited; both operators correct each other	chance of blocking first air still excists	5	2	1	10	0

HP 3, Hospital pharmacy 3; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 780, cumulative RPN after the initial audit; 290, cumulative RPN after the final assessment.

Hosp	ital pharmacy 4	risk as	ssessment after initial audit				results after	final assessment				
	sources of risk	risk reduction	remaining risk after first audit	s o	D	R P N 1	additional risk reduction	remaining risk	s	0	D	R P N 2
A	Air	SC checked once a year by particle measurements, airflow velocity and	1. chance of environment around work zone at rest not in accordance with Grade A air	5 1	2	10	continuous particle counting near to work zone	unlikely	5	1	1	5
		HEPA filter integrity in at rest condition; daily monitoring by settle plate	 materials and equipment disturb the unidirectional airflow and can block first air at critical spots 	52	3	30	no	materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5	2	3	30
В	Worktop SC	disinfection before each work session by wiping with ethanol 70% impregnated wipes	 no daily monitoring by contact plates; disinfection forgotten; contamination by materials used during preparation 	53	4	60	daily monitoring by contact plates; disinfection at the beginning of a working day is registered in a log; disinfection before each new prepared dosage form is regularly audited	unlikely	5	1	1	5
С	Wall and ceiling SC	daily surface disinfection by wiping with ethanol 70% impregnated wipes	1. disinfection forgotten	5 1	2	10	disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	5
D1	Materials with a sterile surface (sterile devices and infusion bags)	unwrapping in front of SC; all operators in background area wear disposable gloves	1. contaminated outer layer	53	2	30	original boxes are unpacked in front of lock with gloved hands; materials are used directly and/or stored in closed cupboards	transfer and storage is not audited	5	1	2	10
			2. parts of outer layer inside SC	53	2	30	aseptic transfer is regularly audited and both operators correct each other	no aseptic transfer into SC by presentation	5	2	1	10
D2	Critical spots (syringe tips, needles and the opening of tubes)		1. contact of critical spots with the work top of SC	54	3	60	no	contact of critical spots with the work top of SC	5	4	3	60
E1	Materials and equipment with a non-	disinfection by spraying with ethanol 70%	1. high surface bioburden before disinfection	53	3	45	no	high surface bioburden before disinfection	5	3	3	45
	sterile surface (ampoules, vials, bottles)		 spraying is an inadequate disinfection technique; disinfection improperly done 	55	4	100	disinfection by wiping; thorough wiping by completely impregnated wipes; disinfection is regularly audited and both operators correct each other	no validated disinfection procedure; no regular surface monitoring of disinfected materials	5	2	3	30
			3. recontamination of disinfected materials	54	2	40	measures to prevent recontamination; measures to prevent changing disinfected and non-disinfected materials; measures are regularly audited and both operators correct each other	unlikely	5	1	1	5
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection of vial stopper in SC by wiping with sterile ethanol 70%	1. no additional disinfection of ampoule necks; additional disinfection improperly done	54	4	80	additional disinfection of ampoule necks	additional disinfection improperly done	5	3	4	60
F	Operator's hands	sterile gloves, which are changed at	1. glove damage	53	3	45	hands of operator in SC are double gloved	unlikely	5	1	1	5
		settle plate	2. surface contamination during putting on aloves	53	3	45	no	surface contamination during putting on aloves	5	3	3	45
			3. surface contamination during preparation	54	2	40	glove disinfection before start of each new preparation and every 15 min during a long preparation; glove disinfection is regularly audited and both operators correct each other	unlikely	5	1	1	5
G	Operator's forearm	wearing cleanroom clothing which is changed every day	1. surface contamination of the worktop	5 3	2	30	operator wears sterile sleeves which are changed after every session	unlikely	5	1	1	5
Н	Working procedure	working with two operators during processing; SOPs; operators trained	1. deviation from SOPs	53	3	45	working according to SOPs is regularly audited; both operators correct each other	SOPs can be improved (more details, in particular of critical activities)	5	2	1	10
		in aseptic techniques; aseptic process simulation with a broth solution	2. touching critical spots	54	4	80	additional training in non-touch working; operators are regularly audited; both operators correct each other	chance of touch still exists	5	2	2	20
			3. SC (downflow), blocking first air at critical spots	53	3	45	prevention of blocking first air is regularly audited; both operators correct each other	chance of blocking first air still exists	5	2	1	10
						825			_	_	_	365

HP 4, Hospital pharmacy 4; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 825, cumulative RPN after the initial audit; 365, cumulative RPN after the final assessment.

Hospi	ital pharmacy 5	risk asses	sment after initial audit					results after fina	al assessment					
	sources of risk	risk reduction	remaining risk after first audit	s	0	D	R P N 1	additional risk reduction	remaining risk	s	0	D	R P N	2
A	Air	SC checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition;	1. chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10	no	chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	1	0
		daily air sampling by settle plate	2. materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5	2	3	30	no	materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5	2	3	3	30
В	Worktop SC	disinfection before each work session by wiping with ethanol 70% impregnated wipes	 no daily monitoring by contact plates; disinfection forgotten; contamination by materials used during preparation 	5	3	4	60	daily monitoring by contact plates; disinfection at the beginning of a working day is registered in a log; disinfection before each new prepared dosage form is regularly audited	unlikely	5	1	1	Ę	5
С	Wall and ceiling SC	daily surface disinfection by wiping with ethanol 70% impregnated wipes	1. disinfection forgotten	5	1	2	10	disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	Ę	5
D1	Materials with a sterile surface (sterile devices and infusion bags)	unwrapping in front of SC	1. contaminated outer layer	5	4	2	40	all operators in background area and anteroom wear disposable gloves; materials are used directly and/or store in closed cupboards	no unpacking original boxes in front of lock with gloved hands; transfer and storage is not audited	5	2	2	2	20
			2. parts of outer layer inside SC	5	3	2	30	aseptic transfer into SC by presentation; aseptic transfer is regularly audited and both operators correct each other	unlikely	5	1	1	Ľ	5
D2	Critical spots (syringe tips, needles and the opening of tubes)		1. contact of critical spots with the work top of SC	5	4	3	60	no	contact of critical spots with the work top of SC	5	4	3	6	50
E1	Materials and equipment with a non- sterile surface	disinfection by wiping with ethanol 70% impregnated wipes	1. high surface bioburden before disinfection	5	3	3	45	ampoules and vials are transferred into the anteroom in their original boxes; materials are used directly and/or stored in closed cupboards	no periodical surface bioburden determination before disinfection; transfer and storage is not audited	5	1	3	1	5
	(ampoules, vials, bottles)		2. disinfection improperly done	5	4	4	80	thorough wiping by a validated disinfection procedure (two towel technique [15]); disinfection is regularly audited and both operators correct each other	no regular surface monitoring of disinfected materials	5	1	3	1	5
			3. recontamination of disinfected materials	5	4	2	40	measures to prevent recontamination; measures are regularly audited and both operators correct each other	risk of changing disinfected and non- disinfected materials	5	2	1	1	0
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection in SC by wiping with sterile ethanol 70%	1. additional disinfection improperly done	5	3	4	60	precisely described and improved additinal disinfection technique; additional disinfection is regularly audited; both operators correct each other	still no assurance of a sterile surface	5	1	2	1	0
F	Operator's hands	sterile gloves, which are changed at	1. glove damage	5	3	3	45	no	glove damage	5	3	3	4	ł5
		least every two hours; daily glove print by settle plate	2. surface contamination during putting on gloves	5	3	3	45	good putting on technique; putting on technique is regularly audited; both operators correct each other	unlikely	5	1	1	Ę	5
			 surface contamination during preparation 	5	4	2	40	glove disinfection before start of each new preparation and every 15 min during a long preparation; glove disinfection is regularly audited and both operators	unlikely	5	1	1	Ľ	5
G	Operator's forearm	wearing cleanroom clothing which is changed every day	1. surface contamination of the worktop	5	3	2	30	operator wears sterile sleeves which are changed after every session	unlikely	5	1	1	L.	5
Н	Working procedure	working with two operators during processing; SOPs; operators trained in aseptic techniques; aseptic process	1. deviation from SOPs	5	3	3	45	accurate and up to date SOPs (enough details, univocal text); working according to SOPs is regularly audited; both operators correct each other	unlikely	5	1	1		5
		simulation with a broth solution	2. touching critical spots	5	4	4	80	additional training in non-touch working; non-touch working is regularly audited; both operators correct each other	still a chance of touch	5	2	2	2	20
			3. SC (downflow), blocking first air at critical spots	5	3	3	45	prevention of blocking first air is regularly audited; both operators correct each other	still a chance of blocking first air	5	2	1	1	0
				_		_	795			_		_	2	80

HP 5, Hospital pharmacy 5; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 795, cumulative RPN after the initial audit; 280, cumulative RPN after the final assessment.

Hosp	ital pharmacy 6	risk asse	ssment after initial audit				results a	ifter final assessment
	sources of risk	risk reduction	remaining risk after first audit	s	D	R P N 1	additional risk reduction	remaining risk
A	Air	LAF checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air	1. chance of environment around work zone at rest not in accordance with Grade A air	5	12	10	no	chance of environment are rest not in accordance with
		sampling by settle plate	2. materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5 2	2 3	30	no	materials and equipment of unidirectional airflow and or critical spots
В	Worktop LAF	disinfection before each work session by wiping with ethanol 70% impregnated wipes; daily monitoring by contact plate	1. disinfection forgotten; contamination by materials used during preparation	5 3	3 3	45	disinfection at the beginning of a working day is registered in a log; disinfection before each new prepared dosage form	disinfection before each ne form is not audited
С	Wall and ceiling LAF	daily surface disinfection by wiping with ethanol 70% impregnated wipes	1. disinfection forgotten	5	1 2	10	disinfection at the beginning of a working day is registered in a log	unlikely
D1	Materials with a sterile surface (sterile devices and infusion bags)	unwrapping partly in front of LAF	1. contaminated outer layer	5 4	1 2	40	all operators in background area wear disposable gloves; original boxes are unpacked in front of lock with gloved hands; materials are used directly and/or stored in closed cupboards	transfer and storage is not
			2. no second operator during processing; parts of outer layer inside LAF	5 4	1 2	40	all materials are unwrapped in front of LAF	transfer is not audited and correct each other
D2	Critical spots (syringe tips, needles and the opening of tubes)		1. contact of critical spots with the work top of LAF	5 4	4 3	60	syringes, needles and open tubes are put down on a sterile pad in LAF	use of a sterile pad is not a don't correct each other
E1	Materials and equipment with a non- sterile surface (ampoules vials	disinfection by wiping with ethanol 70% impregnated wipes	1. high surface bioburden before disinfection	5 3	3 3	45	original boxes are unpacked in front of the lock with gloved hands, materials are put directly into the lock; materials are used directly and/or stored in closed cupboards	no periodical surface biob before disinfection; transfe audited
	bottles)		2. disinfection improperly done	5 4	1 4	80	thorough wiping by a validated disinfection procedure (two towel technique [15])	no regular surface monitor materials; disinfection pro- and operators don't correct
			3. recontamination of disinfected materials	5 4	1 2	40	measures to prevent recontamination; measures to prevent changing disinfected and non- disinfected materials	measures to prevent record changing are not audited; correct each other
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection in LAF by wiping with ethanol 70%	 no use of a sterile disinfectant; additional disinfection improperly done 	5 4	4	80	use of a sterile disinfectant; precisely described and improved additinal disinfection technique	additional disinfection is no don't correct each other
F	Operator's hands	sterile gloves, daily glove print by settle plate	1. gloves are not changed regularly; glove damage	5 4	4 3	60	gloves are changed before each new preparation	no check of glove integrity not audited; operators dor
			2. surface contamination during putting on gloves	5 3	3 3	45	good putting on technique	putting on gloves is not au correct each other
			3. gloves are not changed regularly; surface contamination during preparation	5 !	5 2	50	new gloves before each new preparation	no glove disinfection every preparation; glove disinfect audited and both operators
G	Operator's forearm	wearing cleanroom clothing which is changed every day	1. surface contamination of the worktop	5 3	3 2	30	no	surface contamination of t
Н	Working procedure	SOPs; operators trained in aseptic techniques; aseptic process simulation with a broth solution	deviation from SOPs; no second operator during processing touching critical spots; no second operator during processing	5 3 5 4	3 3 4 4	45 80	accurate and up to date SOPs (enough details, univocal text) additional training in non-touch working	working according to SOP operators don't correct ead non-touch working is not a don't correct each other
			LAF (crossflow), blocking first air at critical spots; no second operator during processing	5 2	2 3	30	no	LAF (crossflow), blocking spots

HP 6, Hospital pharmacy 6; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 820, cumulative RPN after the initial audit; 505, cumulative RPN after the final assessment.

820

t				
	S	0	D	R P N 2
ound work zone at h Grade A air	5	1	2	10
disturb the can block first air at	5	2	3	30
ew prepared dosage	5	2	2	20
	5	1	1	5
t audited	5	1	2	10
esentation; aseptic d operators don't	5	3	2	30
audited; operators	5	2	3	30
urden determination er and storage is not	5	1	3	15
ring of disinfected cedure is not audited ct each other	5	2	4	40
ntamination and operators don't	5	2	2	20
ot audited; operators	5	2	4	40
y; glove handling is n't correct each other	5	3	3	45
udited; operators don't	5	2	3	30
y 15 min during a long ction is not regularly rs don't correct each	5	3	2	30
the worktop	5	3	2	30
Ps is not audited; ich other	5	2	3	30
audited; operators	5	3	4	60
first air at critical	5	2	3	30
	-	-	_	

505

sources of risk risk reduction remaining risk after first audit S O D R P Additional risk reduction remaining risk A Air SC checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest contin accordance with filter integrity in at rest continon; daily air sampling by settle plate 1. chance of environment around work cone at rest not in accordance with filter integrity in at rest continon; daily air air at critical spots 5 1 2 10 no chance of environment arou zone at rest not in accordance with air at critical spots 5 2 3 30 no materials and equipment dis undirectional airflow and can biok first air at critical spots 5 3 4 60 disinfection at the beginning of working day is registered in a log daily glove print by settle plate C Wall and ceiling SC daily surface disinfection by wiping with ethanol 70% impregnated wipes 1. disinfection forgotten variance is the storile 5 1 2 10 no contaminate by working day is registered in a log contaminate by the working day is registered in a log unlikely D1 Materials with a storile surface (sterile devices and infusion backs) 1. contact of critical spots with the work top of SC <t< th=""><th>s work 5 with 5 block 5 ; 5 ed</th><th>5 5</th><th>0</th><th>D 2</th><th>R P N 2 10</th></t<>	s work 5 with 5 block 5 ; 5 ed	5 5	0	D 2	R P N 2 10
A Air SC checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air sampling by settle plate 1. chance of environment around work Grade A air 5 1 2 10 no chance of environment arou zone at rest not in accordance Grade A air B Worktop SC disinfection before each work session by wiping with ethanol 70% impregnated wipes; weekly monitoring by contact plates; aud influsion bads) 1. no daily disinfection forgotten 5 1 2 30 no materials and equipment dis undirectional airflow and can binsfection program disinfection before each work session by wiping with ethanol 70% impregnated wipes; weekly monitoring by contact plates; aud influsion bads) 5 1 2 30 no materials and equipment dis undirectional airflow and can binsfection forgotten 5 1 2 3 4 60 disinfection at the beginning of a working day is registered in a log daily glove print by settle pla contamination by working day is registered in a log daily glove print by settle pla contamination alog D1 Materials with a sterile surface (sterile devices and influsion bads) uniwapping in front of SC 1. contaminated outer layer 5 4 2 40 no contamination of disinfection at the beginning of a working day is registered in a log unilkely D2	d work 5 with 5 block 5 ; 5 ed	5	1 2	2	10
Sampling by settle plate2. materials and equipment disturb the undirectional airflow and can block first air at critical spots52330nomaterials and equipment dis undirectional airflow and can block first air at critical spotsBWorktop SCdisinfection before each work session by wiping with ethanol 70% impregnated wipes; weekly monitoring by contact plates; disinfection by wiping with ethanol 70% impregnated wipes1. no daily monitoring by contact plates; disinfection forgotten; contamination by materials used during preparation51210disinfection at the beginning of a working day is registered in a logdaily glove print by settle plate contamination by materials u during preparationCWall and ceiling SCdaily surface disinfection by wiping with ethanol 70% impregnated wipes1. disinfection forgotten than 07% impregnated wipes51210disinfection at the beginning of a working day is registered in a logunlikelyD1Materials with a sterile surface (sterile devices and infusion baas)unwrapping in front of SC1. contaminated outer layer 2. parts of outer layer inside SC53230nocontaminated outer layer working day is registered in a logD2Critical spots (syringe tips, needles and the opening of tubes)disinfection by wiping with ethanol 70% impregnated wipes1. high surface bioburden before disinfection53345nonohigh surface bioburden befor disinfectionE1Materials and equipment with a non- sterile surface (ampoules, vials, <td>irb the 5 block ; 5 ed</td> <td>5</td> <td>2</td> <td>2</td> <td></td>	irb the 5 block ; 5 ed	5	2	2	
B Worktop SC disinfection before each work session by wiping with ethanol 70% impregnated wipes; weekly monitoring by contact plate: disinfection forgotten; contamination by materials used during preparation 5 3 4 60 disinfection at the beginning of a working day is registered in a log dially glove print by settle plates; disinfection forgotten; contamination by materials used during preparation 5 3 4 60 disinfection at the beginning of a working day is registered in a log dially glove print by settle plates; disinfection by materials used during preparation C Wall and ceiling SC daily surface disinfection by wiping with ethanol 70% impregnated wipes 1. disinfection forgotten 5 1 2 10 disinfection at the beginning of a working day is registered in a log unlikely D1 Materials with a sterile surface (sterile devices and infusion bass) unwrapping in front of SC 1. contaminated outer layer 5 4 2 40 no contaminated outer layer D2 Critical spots (syringe tips, needles and the opening of tubes) unwrapping with ethanol 70% 1. contact of critical spots with the work top of SC 5 3 3 45 60 no contaminated outer layer inside SC E1 Materials and equipment with a nonstrifus burdace (ampoules, vials, botttles) disi	; 5 ed			3	30
C Wall and ceiling SC daily surface disinfection by wiping with ethanol 70% impregnated wipes 1. disinfection forgotten 5 1 2 10 disinfection at the beginning of a working day is registered in a log unlikely D1 Materials with a sterile surface (sterile devices and infusion bags) unwrapping in front of SC 1. contaminated outer layer 5 4 2 40 no contaminated outer layer D2 Critical spots (syringe tips, needles and the opening of tubes) 1. contact of critical spots with the work top of SC 5 4 3 60 no contact of critical spots with top of SC E1 Materials and equipment with a non-sterile surface (ampoules, vials, bottles) disinfection by wiping with ethanol 70% 1. high surface bioburden before disinfection 5 4 3 45 no high surface bioburden before disinfection 2. disinfection improperly done 5 4 4 80 no disinfection improperly done		5	3	3	45
D1Materials with a sterile surface (sterile devices and infusion bags)unwrapping in front of SC1. contaminated outer layer54240nocontaminated outer layerD2Critical spots (syringe tips, needles and the opening of tubes)1. contact of critical spots with the work top of SC53230noparts of outer layer inside SCE1Materials and equipment with a non- sterile surface (ampoules, vials, bottles)disinfection by wiping with ethanol 70% impregnated wipes1. high surface bioburden before disinfection53345nohigh surface bioburden before disinfection improperly done54480nocontamination of disinfected materials	5	5	1	1	5
surface (sterile devices and infusion bads) 2. parts of outer layer inside SC 5 3 2 30 no parts of outer layer inside SC D2 Critical spots (syringe tips, needles and the opening of tubes) 1. contact of critical spots with the work top of SC 5 4 3 60 no contact of critical spots with top of SC E1 Materials and equipment with a non- sterile surface (ampoules, vials, bottles) disinfection by wiping with ethanol 70% impregnated wipes 1. high surface bioburden before disinfection 5 4 4 80 no high surface bioburden before disinfection 2. disinfection improperly done 5 4 4 80 no recontamination of disinfected materials	5	5	4	2	40
D2 Critical spots (syringe tips, needles and the opening of tubes) 1. contact of critical spots with the work top of SC 5 4 3 60 no contact of critical spots with top of SC E1 Materials and equipment with a non-sterile surface (ampoules, vials, bottles) disinfection by wiping with ethanol 70% 1. high surface bioburden before disinfected materials 5 4 3 60 no contact of critical spots with top of SC	5	5	3	2	30
E1 Materials and equipment with a non- sterile surface (ampoules, vials, bottles) disinfection by wiping with ethanol 70% 1. high surface bioburden before disinfection 5 3 3 45 no high surface bioburden before disinfection	e work 5	5	4	3	60
sterile surface (ampoules, vials, bottles)2. disinfection improperly done54480nodisinfection improperly done3. recontamination of disinfected materials54240norecontamination of disinfected materials	5	5	3	3	45
(ampoules, vials, bottles)3. recontamination of disinfected materials54240norecontamination of disinfected materials	5	5	4	4	80
	5	5	4	2	40
E2 Critical spots (vial additional disinfection in SC by wiping with storpers and ampoule necks) additional disinfection in SC by wiping with 1. additional disinfection improperly done 5 3 4 60 no additional disinfection improperly done 5 3 4 60 no	rly done 5	5	3	4	60
FOperator's handssterile gloves, which are changed at least1. glove damage53345noglove damage	5	5	2	3	30
every hour; daily glove print by settle plate 2. surface contamination during putting 5 3 3 45 no surface contamination during on gloves on gloves	outting 5	5	2	3	30
3. surface contamination during 5 4 2 40 no surface contamination during preparation preparation preparation preparation preparation	5	5	3	3	45
G Operator's forearm wearing cleanroom clothing which is changed every day 1. surface contamination of the worktop 5 2 3 30 operator wears a sterile overcoat, unlikely which is changed after every session	5	5	1	1	5
H Working procedure working with two operators during 1. deviation from SOPs 5 3 3 45 no deviation from SOPs		5	3	3	45
processing; SOPs; operators trained in 2. touching critical spots 5 4 4 80 no touching critical spots	5	5	4	4	80
aseptic techniques; aseptic process simulation with a broth solution 3. SC (downflow), blocking first air at critical spots 5 3 3 45 no blocking first air at critical spots	5	5	3	3	45

HP 7, Hospital pharmacy 7; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 795, cumulative RPN after the initial audit; 725, cumulative RPN after the final assessment.

Hosp	ital pharmacy 8	risk assessm	ent after initial audit					results after fina	l assessment				
	sources of risk	risk reduction	remaining risk after first audit	s	0	D	R P N 1	additional risk reduction	remaining risk	s	0	D	R P N 2
A	Air	LAF checked 2 times a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air sampling by	1. chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10	no	chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10
		settle plate	 materials and equipment disturb the unidirectional airflow and can block first air at critical spots 	5	2	3	30	correct position of materials after investigations by airflow visualization in worst case situation; position of materials is regularly audited and both operators correct each other	unlikely	5	1	1	5
В	Worktop LAF	disinfection before each work session by wiping with ethanol 70% impregnated wipes; weekly monitoring by contact plate; disinfection at the beginning of a working day is registered in a log	 no daily monitoring by contact plates; contamination by materials used during preparation 	5	3	3	45	disinfection before each new prepared dosage form; disinfection before each new prepared dosage form is regularly audited	no daily monitoring by contact plates	5	1	2	10
С	Wall and ceiling LAF	daily surface disinfection by wiping with ethanol 70% impregnated wipes; disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	5	no	unlikely	5	1	1	5
D1	Materials with a sterile surface (sterile devices and infusion bags)	unwrapping in front of LAF	1. contaminated outer layer	5	4	2	40	all operators in background area and anteroom wear disposable gloves; original boxes are unpacked in front of lock with gloved hands; materials are used directly and/or stored in closed cupboards	transfer and storage is not audited	5	1	2	10
			2. no second operator during processing; parts of outer layer inside LAF	5	3	2	30	no	no second operator during processing; parts of outer layer inside LAF	5	3	2	30
D2	Critical spots (syringe tips, needles and the opening of tubes)		1. contact of critical spots with the work top of LAF	5	4	3	60	no	contact of critical spots with the work top of LAF	5	4	3	60
E1	Materials and equipment with a non- sterile surface	disinfection in anteroom by wiping with ethanol 70% impregnated wipes; well controlled transfer process of disinfected materials into background	1. high surface bioburden before disinfection	5	3	3	45	ampoules and vials are transferred into the anteroom in their original boxes; materials are used directly and/or stored in closed cupboards	no periodical surface bioburden determination before disinfection; transfer and storage is not audited	5	1	3	15
	(ampoules, vials, bottles)	area; measures to prevent recontamination; measures to prevent changing disinfected and non-disinfected materials	2. disinfection improperly done	5	4	4	80	Thorough wiping by completely impregnated wipes; regular surface monitoring of disinfected materials; disinfection is regularly audited	no validated disinfection procedure	5	2	1	10
			3. measures to prevent recontamination and changing are not audited	5	2	2	20	measures are regularly audited and both operators correct each other	unlikely	5	1	1	5
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection in LAF by wiping with sterile ethanol 70%	 no additional disinfection of ampoule necks; additional disinfection improperly done 	5	4	4	80	additional disinfection of ampoule necks; precisely described and improved additinal disinfection technique; additional disinfection is regularly audited	still no assurance of a sterile surface; no second operator during processing	; 5	1	3	15
F	Operator's hands	sterile gloves, which are changed at least every hour; daily glove print by settle plate	1. glove damage	5	3	3	45	gloves integrity is tested immediately after putting them on and during processing; glove handling is regularly audited	no second operator during processing; parts of outer layer inside LAF	5	1	2	10
			2. surface contamination during putting on gloves	5	3	3	45	good putting on technique; putting on technique is regularly audited	no second operator during processing; parts of outer layer inside	5 e	1	2	10
			 surface contamination during preparation 	5	4	2	40	glove disinfection before start of each new preparation and every 15 min during a long preparation; glove disinfection is regularly audited	unlikely	5	1	1	5
G	Operator's forearm	wearing cleanroom clothing which is changed every day	1. surface contamination of the worktop	5	3	2	30	no	surface contamination of the worktop	5	2	3	30
Н	Working procedure	SOPs; operators trained in aseptic techniques; aseptic process simulation with a broth solution	1. deviation from SOPs; no second operator during processing	5	3	3	45	accurate and up to date SOPs (enough details, univocal text); working according to SOPs is regularly audited	no second operator during processing	5	1	2	10
			2. touching critical spots; no second	5	4	4	80	additional training in non-touch working; non-touch working	still a chance of touch; no second	5	2	3	30
			3. LAF (crossflow), blocking first air at critical spots; no second operator during processing	5	2	3	30	prevention of blocking first air is regularly audited	no second operator during processing	5	1	2	10
L		<u></u>	IF:	1			760	A	1		<u> </u>		280

HP 8, Hospital pharmacy 8; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 760, cumulative RPN after the initial audit; 280, cumulative RPN after the final assessment.

Hospital pharmacy 9		risk assessment after initial audit					results after final assessment							
	sources of risk	risk reduction	remaining risk after first audit	s	0	D	R P N 1	additional risk reduction	remaining risk	s	0	D	F F N	2 2
A	Air	LAF checked once a year by particle measurements, airflow velocity and HEPA filter integrity in at rest condition; daily air sampling by settle plate	1. chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	10	no	chance of environment around work zone at rest not in accordance with Grade A air	5	1	2	1(D
			2. materials and equipment disturb the unidirectional airflow and can block first air at critical spots	5	2	3	30	correct position of materials after investigations by airflow visualization in worst case situation; position of materials is regularly audited	unlikely	5	1	1	5	
В	Worktop LAF	disinfection before each work session by wiping with isopropyl alcohol 70% impregnated wipes; daily monitoring by contact plate; disinfection at the beginning of a working day is registered in a log	1. contamination by materials used during preparation	5	3	2	30	disinfection before each new prepared dosage form; disinfection before each new prepared dosage form is regularly audited	unlikely	5	1	1	5	
С	Wall and ceiling LAF	daily surface disinfection by wiping with isopropyl alcohol 70% impregnated wipes; disinfection at the beginning of a working day is registered in a log	unlikely	5	1	1	5	no	unlikely	5	1	1	5	
D1	Materials with a sterile	unwrapping in front of LAF; all operators in	1. contaminated outer layer	5	2	2	20	no	contaminated outer layer	5	2	2	2	<mark>0</mark>
	surface (sterile devices and infusion bags)	background area wear disposable gloves; materials are used directly and/or store in closed cupboards; aseptic transfer is regularly audited	2. no second operator during processing; parts of outer layer inside LAF	5	3	2	30	no	no second operator during processing; parts of outer layer inside LAF	5	3	2	30)
D2	Critical spots (syringe tips, needles and the opening of tubes)		1. contact of critical spots with the work top of LAF	5	4	3	60	putting down syringes, needles and open tubes on a sterile pad in LAF; use of sterile pad is regularly audited	no second operator during processing	5	1	2	1()
E1	Materials and equipment with a non-sterile surface	disinfection by wiping with isopropyl ethanol 70% impregnated wipes; disinfection is regularly audited;	 high surface bioburden before disinfection 	5	3	3	45	no	high surface bioburden before disinfection	5	3	3	4	5
	(ampoules, vials, bottles)	measures to prevent changing disinfected and non- disinfected materials which are audited regularly	2. disinfection improperly done	5	4	4	80	thorough wiping by a validated disinfection procedure (two towel technique [15]); regular surface monitoring of disinfected materials; disinfection is regularly audited	unlikely	5	1	1	5	
			3. recontamination of disinfected materials	5	3	2	30	measures to prevent recontamination; measures are regularly audited	unlikely	5	1	1	5	
E2	Critical spots (vial stoppers and ampoule necks)	additional disinfection in LAF by wiping with sterile ethanol 70%; additional disinfection is regularly audited	1. additional disinfection can be improved	5	2	3	30	precisely described and improved additinal disinfection technique	still no assurance of a sterile surface; no second operator during processing	5	1	3	1	5
F	Operator's hands	sterile gloves, which are changed at least every hour; daily glove print by settle plate	1. glove damage	5	3	3	45	gloves integrity is tested immediately after putting them on and during processing; glove handling is regularly audited	no second operator during processing	5	1	2	1(D
			2. surface contamination during putting on gloves	5	3	3	45	good putting on technique; putting on technique is regularly audited	no second operator during processing	5	1	2	1(C
			3. surface contamination during preparation	5	4	2	40	glove disinfection before start of each new preparation and and every 15 min during a long preparation; glove disinfection is regularly audited	unlikely	5	1	1	5	
G	Operator's forearm	waring cleanroom clothing which is changed every day	1. surface contamination of the worktop	5	3	2	30	operator wears sterile sleeves which are changed after every session	unlikely	5	1	1	5	
Н	Working procedure	SOPs; operators trained in aseptic techniques; aseptic process simulation with a broth solution; non- touch working and prevention of blocking first air are	1. deviation from SOPs; no second operator during processing	5	3	3	45	accurate and up to date SOPs (enough details, univocal text); working according to SOPs is regularly audited	no second operator during processing	5	1	2	1()
		regularly audited	2. touching critical spots; no second operator during processing	5	3	3	45	additional training in non-touch working	still a chance of touch; no second operator during processing	5	2	3	3)
			3. LAF (crossflow), blocking first air at critical spots; no second operator during processing	5	1	2	10	no	no second operator during processing	5	1	2	1()
							630						23	5

HP 9, Hospital pharmacy 9; S, severity; O, occurrence; D, detection; RPN, Risk Prioritization Number. 630, cumulative RPN after the initial audit; 235, cumulative RPN after the final assessment.